

# Private Regulation and Foreign Conduct

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## I. INTRODUCTION

The United States imports over \$49 billion in FDA-regulated food products<sup>1</sup> and over \$71 billion in USDA-regulated agricultural products each year.<sup>2</sup> Put in other terms, as of 2005, 15% of all food consumed in the United States was imported. This is an increase from only 11% to 12% a decade earlier.<sup>3</sup> More strikingly, these import figures include 60% of U.S. consumption of fresh fruits and vegetables and more than

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1. U.S. FOOD & DRUG ADMIN., FOOD PROTECTION PLAN: AN INTEGRATED STRATEGY FOR PROTECTING THE NATION'S FOOD SUPPLY (2007), *available at* <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>.

2. *See* U.S. Dep't of Agric., *Foreign Agricultural Trade of the United States (FATUS): Monthly Summary*, <http://www.ers.usda.gov/Data/FATUS/monthlysummary.htm> (last visited May 17, 2010) (listing \$71.913 billion in imported agricultural products in calendar year 2007 and \$80.488 billion in calendar year 2008). The USDA numbers include some food products also regulated by FDA, such as grains, fruit, and seeds, as well as some products not used as food, such as animal hides and rubber. *See id.* n.1. A current number limited to meat, eggs, and poultry does not appear to be available.

3. GEOFFREY S. BECKER, CONG. RESEARCH SERV., FOOD AND AGRICULTURAL IMPORTS FROM CHINA 5 (2008), *available at* <http://www.fas.org/sgp/crs/row/RL34080.pdf>.

75% of U.S. seafood consumption.<sup>4</sup> From China alone, the United States imported \$4.9 billion in agricultural and seafood products in 2007: roughly a fourfold increase in the past decade.<sup>5</sup>

It is, in fact, China that has given imported-food safety a new political relevance in the United States. Although food products imported from China have so far been traced to relatively few serious U.S. injuries, problems in related product categories are a significant ground for concern. Since the beginning of 2007, this includes 246 deaths from contaminated blood thinner,<sup>6</sup> the death of large numbers of dogs and cats from pet food contaminated with melamine,<sup>7</sup> and the discovery of diethylene glycol—a poisonous industrial chemical—in toothpaste.<sup>8</sup>

Within China itself, the story is significantly worse. In late 2008 and early 2009, infant formula and other milk products contaminated with melamine killed at least six children and sickened almost 300,000 people, many of them young children.<sup>9</sup> The health consequences were

4. U.S. FOOD & DRUG ADMIN., *supra* note 1. Fresh produce and seafood are both categories that present significant opportunities for contamination and spoilage.

5. BECKER, *supra* note 3, at 5.

6. WAYNE M. MORRISON, CONG. RESEARCH SERV., CHINA-U.S. TRADE ISSUES 11 (2009), available at <http://www.fas.org/sgp/crs/row/RL33536.pdf>.

7. As of May 2009, the actual number of dog and cat deaths confirmed by FDA as caused by melamine-tainted pet food was sixteen. U.S. Food & Drug Admin., *FDA's Ongoing Pet Food Investigation* 4 (Apr. 16, 2007), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/ucm048201.pdf>. However, press reports indicated that melamine was suspected in “perhaps thousands” of pet deaths during this time, *Pet-Food Companies Settle Lawsuit*, WALL ST. J., May 24, 2008, at A2, and FDA indicated that the sixteen confirmed deaths might be an extremely conservative number. U.S. Food & Drug Admin., *supra*, at 4 (“FDA recognizes that there may be many more pet illnesses and deaths than the 16 deaths it has confirmed so far.”).

8. U.S. Food & Drug Admin., *Toothpaste Imported from China May Contain Diethylene Glycol* (June 13, 2007), <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm153155.htm> (describing diethylene glycol as “a central nervous system depressant and potent kidney and liver toxin”). This is perhaps a perverse incident of history repeating itself. Diethylene glycol was the poisonous substance involved in the elixir sulfanilamide incident that is generally thought to be the event that led to the passage of the Food, Drug, and Cosmetic Act of 1938. See Carol Ballentine, *Taste of Raspberries, Taste of Death: The 1937 Elixir Sulfanilamide Incident*, FDA CONSUMER MAG., June 1981, available at <http://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/Origin/ucm125604.doc>.

9. James T. Areddy, *Authorities in China Likely Knew of Bad Milk*, WALL ST. J., Jan. 6, 2010, at A10; MORRISON, *supra* note 6, at 12. Recent news reports indicate that as of early 2010 Chinese authorities were still discovering tremendous quantities of contaminated milk powder. See, e.g., Gordon Fairclough, *China Finds Tons of Tainted Milk Powder*, WALL ST. J., Feb. 8, 2010, at A10 (indicating that Chinese authorities had

significant. Over 50,000 of the affected individuals were hospitalized,<sup>10</sup> and it appears that many may suffer lifelong kidney problems from the incident. Many less dramatic incidents in recent years have made the Chinese public understandably suspicious about food safety.<sup>11</sup> Given the huge volume of annual imports, it seems only a matter of time before one of the food-related health problems now common in China surfaces in Chinese products exported to the United States.

Similar problems can be expected with foods imported from other countries with underdeveloped domestic regulatory structures. Beyond China, the United States has confirmed recent U.S. outbreaks of hepatitis A traced to green onions from Mexico,<sup>12</sup> salmonella traced to cantaloupe from Mexico,<sup>13</sup> hepatitis A traced to strawberries from Mexico,<sup>14</sup> and cyclospora traced to raspberries from Guatemala.<sup>15</sup> Additionally, the dramatic rise in aquaculture operations in recent years—many of which rely on antibiotics, fungicides, and pesticides not approved for use in the United States—suggests that there may be additional, latent risks associated with imported seafood.<sup>16</sup>

Moreover, many of the most common food safety problems can be traced to more fundamental environmental problems, such as unclean water and contaminated soil. Unclean water is a major concern for both microbial and chemical contamination. On the microbial side, many common disease-causing pathogens can be traced to human or animal waste in water supplies. On the chemical side, many developing countries are not successful in blocking the discharge of large volumes of industrial chemicals into oceans, lakes, rivers, and streams.<sup>17</sup> To the

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“seized more than 60 tons” of the contaminated powder and were seeking to track down “[a]n additional nearly 100 tons” that had already been sold by a particular company).

10. MORRISON, *supra* note 6, at 12.

11. Waikeng Tam & Dali Yang, *Food Safety and the Development of Regulatory Institutions in China*, 29 ASIAN PERSP. 5, 5–9 (2005).

12. LINDA CALVIN ET AL., U.S. DEP’T OF AGRIC., THE ECONOMICS OF FOOD SAFETY: THE CASE OF GREEN ONIONS AND HEPATITIS A OUTBREAKS 2 (2004).

13. Linda Calvin, *Produce, Food Safety, and International Trade: Response to U.S. Foodborne Illness Outbreaks Associated with Imported Produce*, in INTERNATIONAL TRADE AND FOOD SAFETY: ECONOMIC THEORY AND CASE STUDIES 74, 85–88 (Jean C. Buzby ed., 2003).

14. *Id.* at 83–85.

15. *Id.* at 80–83.

16. See generally FOOD & WATER WATCH, IMPORT ALERT: GOVERNMENT FAILS CONSUMERS, FALLS SHORT ON SEAFOOD INSPECTIONS 14 (2007).

17. See, e.g., Elizabeth C. Economy, *The Great Leap Backward?: The Costs of China’s Environmental Crisis*, FOREIGN AFFS., Oct. 2007, at 38, 42–44.

extent these industrial chemicals build up in the soil, particular plots of land can become unfit for safe agricultural production.<sup>18</sup>

Given the rising share of U.S. food production that is imported from developing countries, the U.S. faces increasing risks to its food supply from problems inherent in food production in less developed economies. This certainly includes substantial risks of isolated breakouts of foodborne illnesses that sicken hundreds of people, killing a smaller portion of them. More frighteningly, the recent infant formula crisis in China serves as a stark reminder of more catastrophic outcomes: a single adulterated product can cause potentially permanent injuries in hundreds of thousands of people.

These events have focused attention on food safety reform. Current U.S. imported-food safety policy is based heavily on ex post measures such as border inspections,<sup>19</sup> tort liability, and the threat of aggressive investigations<sup>20</sup> into significant outbreaks of foodborne illness.<sup>21</sup> Yet many modern food safety problems are difficult to detect through preconsumer testing,<sup>22</sup> and the vagaries of international business make it

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18. *Id.* at 42 (“As much as ten percent of China’s farmland is believed to be polluted, and every year 12 million tons of grain are contaminated with heavy metals absorbed from the soil.”).

19. I classify border inspections as ex post measures because they can at best check the outcome of the production process. Although these are not as purely ex post as measures such as tort liability, which take effect only where there is an actual harm to the consumer, they are more closely related to these ex post measures than to ex ante regulatory requirements. Moreover, for imported products the cleanest ex ante/ex post distinction appears to be a classification of measures in the territory of the importing country as ex post and classification of measures in the territory of the exporting country as ex ante.

20. In the case of a significant outbreak, civil or criminal penalties might be imposed for violation of ex ante requirements. However, the virtual lack of enforcement except in response to an outbreak suggests that these are better analyzed as ex post requirements.

21. *See infra* Part III.A.

22. The need to rely on production processes comes from limits on both technology and resources. Border inspections, an outcome-based regulatory measure, can be reasonably effective as a way of monitoring for known contaminants that are likely to be spread evenly through a particular shipment of food. Pesticide residues are a classic example. If an appropriately large sample from a shipment of apples does not have excessive pesticide residues, a border inspector can be reasonably confident that the shipment overall does not have excessive residues. In contrast to pesticide residues, microbial contaminants such as *E. coli* or hepatitis A might be present in only a small part of a shipment, making sampling strategies ineffective. Chemicals not typically used in food production, such as melamine, cause a related problem. Unless there has been a recent problem with a particular chemical, border inspectors are unlikely to test for it even if a test is easily available. For example, there appears to be some evidence that aquaculture

difficult to translate outcome-based liability into ex ante standards of care. Accordingly, there appears to be an emerging consensus that an effective food safety regime must find a way to set and enforce ex ante requirements for production processes abroad.<sup>23</sup>

There is no consensus, however, on how best to enforce these ex ante requirements. Current proposals move in three directions, relying to different degrees on three basic regulatory strategies: (1) direct extraterritorial regulation; (2) delegation of regulatory authority to private entities; and (3) delegation of regulatory authority to foreign government agencies.<sup>24</sup>

For the first strategy, direct extraterritorial regulation, FDA has already moved toward expanding its geographic reach. The agency has set up small foreign offices in several food-exporting countries; pending legislation directs FDA to continue this process<sup>25</sup> and to develop a dedicated staff of inspectors for the specific purpose of inspecting foreign food facilities.<sup>26</sup> With respect to the second strategy, delegation to private entities, FDA is in the process of implementing a voluntary third-party certification program for foods, and pending legislation would give the agency substantial discretion to require third-party certification of many food imports as a condition for market entry.<sup>27</sup> As to the third strategy, delegation to a foreign government agency, FDA is already focusing additional resources on helping to build foreign regulatory capacity. Pending legislation would give FDA authority to determine whether foreign regulatory systems provide safety levels equivalent to the U.S. system<sup>28</sup> and to permit foreign government agencies to act as third-party certifiers for market entry.<sup>29</sup> Although each of these strategies may have some role to play, it is not clear that current proposals give sufficient thought to how to allocate resources between these three options.

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operations in certain countries are regularly changing the chemical additives they use to stay ahead of European testing regimes. See FOOD & WATER WATCH, *supra* note 16, at 12–13.

23. See generally *infra* Part IV.B (discussing two pending food safety bills relying on ex ante regulatory strategies).

24. A pure thought experiment might also include a fourth option, delegation to a treaty-based international organization. Up to this point, states have been extremely reluctant to grant direct regulatory enforcement powers to international organizations. There does not appear to be any reason to believe this will change in the foreseeable future—particularly in an area, such as food safety regulation, requiring a broad regulatory footprint for effective enforcement. An important exception might be limited, regionally based supranational organizations such as the European Union.

25. S. 510, 111th Cong. § 309 (2009).

26. H.R. 2749, 111th Cong. § 208 (2009).

27. See *infra* notes 127, 131, and accompanying text.

28. See *infra* note 130 and accompanying text.

29. See *infra* note 131 and accompanying text.

The Article proceeds as follows. Part II examines regulatory enforcement generally, viewing the problem through the lens of two basic decisions: whether to target behaviors or outcomes, and whether to rely on direct enforcement or third-party monitoring. Part III turns to imported-food safety. It begins with an overview of current U.S. policy and then examines the effects of foreign production on the choice between ex post and ex ante regulatory strategies. Because of the limits of tort law for regulating multinational activities, ex ante regulation may be more important for imports than for domestically produced products. Part IV focuses on options for ex ante regulation of imported food. It sets out three regulatory strategies and three principal-agent problems that should influence the choice between them. Direct extraterritorial regulation, delegation to a private entity, and delegation to a foreign government agency are the three regulatory strategies included in current reform proposals. The three key principal-agent problems are the regulatory license problem, interest group capture, and the reality of bribery and threats in many food-exporting countries. Part V examines these three principal-agent problems in more detail, demonstrating that they play out in different and somewhat unexpected ways under each of the basic regulatory strategies. Part VI touches briefly on the role of international trade law. Finally, Part VII concludes with some observations on the relationship between funding decisions, delegated regulation, and the scope of government.

## II. FORMS OF REGULATION

Traditional regulation is out of fashion; alternative regulatory instruments are all the rage. Regulated parties are instructed to meet performance standards,<sup>30</sup> identify hazards and mitigate risks, and avoid tort liability. In short, regulated parties are given an ultimate objective and instructed to use judgment to meet that objective.

Yet judgment is a scarce resource and may be even scarcer at low levels in a firm's hierarchy—the very levels at which many risk-related decisions must be made.<sup>31</sup> Moreover, it can be costly to monitor the

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30. See Exec. Order No. 12,866, 58 Fed. Reg. 190 § 1(b)(8) (Oct. 4, 1993).

31. Cf. Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking, and Accountability in the Administrative State*, 56 DUKE L.J. 377, 413–26 (2006).

exercise of judgment by observing final outcomes. At times, the cost of monitoring for negative outcomes is likely to exceed the cost of monitoring for undesirable behavior likely to produce negative outcomes. This suggests that, in at least some regulatory areas, traditional regulation may be socially efficient.

In particular, it may be less expensive to monitor the production processes used by firms than to test the quality of products those firms produce. In situations where the specified processes are relatively inexpensive but the consequences of failing to follow those processes are costly, regulation of behaviors should be preferred over regulation of outcomes. Possible examples include requirements for hand washing in food service establishments, using specific grades of material in home construction, and keeping frozen meat within a specific temperature range during transport.

A focus on the importance of monitoring production processes raises a separate question: who should do the monitoring? Despite a general tendency to look to governments to monitor regulatory compliance, this is not the only option. There are numerous situations in which governments delegate regulatory authority, either to private parties or to other governments.<sup>32</sup> There are also numerous private entities that enforce “voluntary” regimes that permit parties to opt in to a higher level of regulation than provided by the relevant state.<sup>33</sup>

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32. Cf. R.H. Coase, *The Nature of the Firm*, 4 *ECONOMICA* (n.s.) 386, 393 (1937).

33. Voluntary regimes do not exercise authority directly delegated by the state. Instead, they rely on control of some type of claim in product labeling or advertising, often registered as a certification mark, to require parties to conform to specific behavioral requirements. See generally Margaret M. Blair et al., *The New Role for Assurance Services in Global Commerce*, 33 *J. CORP. L.* 325, 336–39 (2008) (noting that a significant third-party certification industry has developed in response to market pressures and legal risk associated with international business); Irina D. Manta, *Privatizing Trademarks*, 51 *ARIZ. L. REV.* 381, 402–04 (2009) (discussing relationship between certification marks and the trademark registration system). Regular audits are frequently required. Examples are numerous and are often tied to conduct that occurs, at least in part, in a foreign country. Companies that wish to use the “Fair Trade” label must comply with requirements set by the Fairtrade Labelling Organization and its affiliated entities. See Fairtrade Labelling Orgs. Int’l, *What Is Fairtrade?*, [http://www.fairtrade.net/what\\_is\\_fairtrade.html](http://www.fairtrade.net/what_is_fairtrade.html) (last visited May 18, 2010). Those who wish to use the label of the Forest Stewardship Council to assert that their wood products are sustainably produced must comply with the requirements set out by that organization. See generally BENJAMIN CASHORE ET AL., *GOVERNING THROUGH MARKETS: FOREST CERTIFICATION AND THE EMERGENCE OF NON-STATE AUTHORITY* (2004). Similarly, those who wish to use the label of the Marine Stewardship Council (MSC) to assert that seafood products were sustainably produced must comply with that organization’s requirements. See Marine Stewardship Council, *MSC Environmental Standard for Sustainable Fishing*, <http://www.msc.org/about-us/standards/standards/msc-environmental-standard> (last visited May 18, 2010). Companies that use a certification mark without approval of the appropriate



The possibility for third-party enforcement of traditional regulation is apparent when considering the intersection of regulatory targets and monitoring regimes. Broadly speaking, regulatory approaches can target behaviors or outcomes,<sup>34</sup> and can rely on government oversight or third-party monitoring.

	<b>Behaviors (ex ante)</b>	<b>Outcomes (ex post)</b>
<b>Direct monitoring</b>	Traditional regulation	Outcome-based regulation
<b>Third-party monitoring</b>	Delegated regulation	Tort liability

These four quadrants represent the spectrum of methods that a regulator can use to affect incentives for regulatory compliance.<sup>35</sup> This typology is independent of the rule/standard distinction: rule-like requirements and standard-like requirements exist in each of these quadrants.<sup>36</sup> The horizontal axis—moving left to right between columns—represents the target of regulation. If a regulatory regime monitors behavior, the subject of regulation is not out of compliance if that behavior results in a socially undesirable outcome. If a regulatory regime targets outcomes, the subject is expected to use all legally permitted methods to reach that outcome. If the subject nonetheless fails to reach

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organization are liable for trademark infringement. See 3 J. THOMAS MCCARTHY, MCCARTHY ON TRADEMARKS AND UNFAIR COMPETITION § 19:92.50 (4th ed. 2009).

34. Cf. Kenneth A. Bamberger & Andrew T. Guzman, *Keeping Imports Safe: A Proposal for Discriminatory Regulation of International Trade*, 96 CAL. L. REV. 1405, 1411–14 (2008) (distinguishing “production lever” and “outcome lever” as regulatory approaches).

35. These are, of course ideal types: many real-world regulatory programs will draw on components of both. *Qui tam* actions under the federal False Claims Act and state law negligence per se suits are bottom-right quadrant actions that rely on standards set out by top-left quadrant regulatory methods. Hazard Analysis & Critical Control Point (HACCP) requirements are a form of ex ante regulation where the government asks companies to develop their own regulatory programs but focuses its monitoring on compliance with those programs rather than ultimate outcomes. See generally 21 C.F.R. § 120 (HACCP requirements for juice); *id.* § 123 (HACCP requirements for seafood).

36. On the rule/standard distinction, see Adam B. Cox & Thomas J. Miles, *Judicial Ideology and the Transformation of Voting Rights Jurisprudence*, 75 U. CHI. L. REV. 1493, 1506–07 (2008).

that outcome, the subject is strictly liable for the regulatory violation. No amount of best efforts or due care is sufficient to escape liability.

The vertical axis—moving up and down between rows—represents the method for monitoring regulatory compliance.<sup>37</sup> The divide between direct and third-party oversight is usually thought of as the torts-versus-regulation debate.<sup>38</sup> Traditional regulation and outcome-based regulation are enforced through direct oversight,<sup>39</sup> while tort law—as a method of affecting ex ante incentives, rather than of compensating for harms—relies on the threat of private lawsuit to encourage parties to avoid harming others. What is interesting when looking at the chart vertically, however, is that there appears to be a basic regulatory approach—delegated regulation—that has been neglected in academic literature.<sup>40</sup> Outside of a few specific regulatory areas,<sup>41</sup> there does not appear to be a significant literature exploring the ramifications of delegated regulation as a matter of institutional design.<sup>42</sup>

Although the analogy is not perfect, it may be useful to think of the vertical axis as representing something akin to the “make-or-buy”

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37. Cf. Coase, *supra* note 32, at 397–98.

38. See generally Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. LEGAL STUD. 357 (1984).

39. Public oversight can, of course, be backed up by civil fines, criminal penalties, or some combination of the two.

40. Partial exceptions include Lawrence A. Cunningham, *Private Standards in Public Law: Copyright, Lawmaking and the Case of Accounting*, 104 MICH. L. REV. 291 (2005) (criticizing government reliance on private standards not available for free to the public); Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. REV. 543, 636–43, 657–64 (2000) [hereinafter Freeman, *Private Role*] (discussing role of private actors in regulatory standard-setting and enforcement); Jody Freeman, *Private Parties, Public Functions and the New Administrative Law*, 52 ADMIN. L. REV. 813 (2000) [hereinafter Freeman, *New Administrative Law*] (same); Frank Partnoy, *Second-Order Benefits from Standards*, 48 B.C. L. REV. 169 (2007) (arguing that focus of policymakers should be on second-order risks associated with private standards incorporated into a public regulatory scheme); Sidney A. Shapiro, *Outsourcing Government Regulation*, 53 DUKE L.J. 389 (2003) (applying transaction-cost analysis and arguing that a decision to outsource standard-setting or enforcement should be conceptualized as a make-or-buy decision); Lior Jacob Strahilevitz, “How’s My Driving?” for Everyone (and Everything?), 81 N.Y.U. L. REV. 1699 (2006) (proposing expanded use of reputation-tracking technologies to permit private citizens to regulate antisocial behavior in various contexts). On the relationship between delegated regulation and the “gatekeeper” literature, see *infra* note 57.

41. See JOHN C. COFFEE, JR. ET AL., *SECURITIES REGULATION: CASES AND MATERIALS* 57–61 (10th ed. 2007) (discussing advantages and disadvantages of the SEC’s reliance on self-regulatory organizations).

42. Although there is a vibrant literature examining public-private partnerships, the focus has primarily been on the blurring of the distinction between public and private in many regulatory areas. See e.g., Freeman, *Private Role*, *supra* note 40, at 545–48; Freeman, *New Administrative Law*, *supra* note 40, at 842–43.

decision.<sup>43</sup> When a government chooses to delegate regulatory authority, it does not typically purchase regulation on the open market by paying directly for regulatory services. Instead, it sets up a situation where regulated parties pay a private party for services that would otherwise be provided by the government out of general tax revenues.<sup>44</sup> In other words, a decision to delegate regulatory authority to a private party has both efficiency consequences and distributive consequences. The efficiency consequences track closely with the traditional make-or-buy decision. In some cases it will be more efficient to provide regulation in-house; in others it will be more efficient to arrange to have that service provided by private parties. The distributive consequences, however, are a set of consequences beyond those contemplated in the traditional make-or-buy situation. A decision to delegate regulatory authority to a private party typically shifts the burden of funding regulation from general tax revenues to the regulated industry and its consumers.<sup>45</sup>

Moreover, delegated regulation may have advantages when a state seeks to regulate conduct that takes place in a foreign country. By enlisting third parties to monitor compliance, it may be possible to regulate activities largely unreachable by direct regulation. However, there may also be inherent limits on such a program that are not recognized in current legislative proposals.

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43. Cf. Shapiro, *supra* note 40, at 400–01. For the reasons set out in the text, I differ with Shapiro in emphasizing the distributive consequences of decisions to privatize regulatory functions.

44. Here, a caveat is in order. Delegated regulation does not require a shift from taxpayer to industry funding and is not the only circumstance where this can occur. It is theoretically possible for the government to set up a private regulatory authority and fund it out of general tax revenues, although this does not appear to be a frequent occurrence. More importantly, there are several regulatory areas in which industry “user fees” are used to fund traditional public regulation. Significant examples include users fees associated with applications to market prescription drugs and medical devices.

45. In other words, it becomes something of an “I make” or “you buy” decision. Cf. Sam Scott Miller, *Self-Regulation of the Securities Markets: A Critical Examination*, 42 WASH. & LEE L. REV. 853, 855 (1985).

## A. Domestic Law

### 1. Traditional Regulation

Traditional regulation is what most people think of when they think of laws or regulations. A typical speed limit is one example. If a highway has a maximum speed limit of fifty-five miles per hour, I may not drive any faster without risking a ticket. It does not matter that I might be a particularly skilled driver or that there is no one else on the road. I can be ticketed for going sixty miles per hour no matter how safe that speed might be.

As the speed limit example suggests, traditional regulation is a tremendously important regulatory tool in modern society. Car accidents impose substantial externalities, and many people believe themselves to be safer drivers than they are.<sup>46</sup> Because of this, any regulatory system that punishes people only when they cause accidents is likely to result in many people driving faster than the socially optimal level. Although it would theoretically be possible to impose fines—or tort damages—for accidents at such a level that people would be sufficiently incentivized to drive slowly, this is unlikely to succeed in practice. Bounded rationality suggests that many people—particularly those who are young, old, impaired by alcohol, or simply running late—will drive too fast even if penalties for accidents are harsh. It is perhaps because of this that speed limits have repeatedly been shown to be an effective means of reducing traffic accidents. Whatever the problems of traditional regulation in particular regulatory areas are, it is unlikely to be socially efficient to abandon it as a regulatory tool.<sup>47</sup>

Despite its advantages, traditional regulation has frequently been maligned in academic and policy circles. The most effective sustained critique may be in the area of “command-and-control” environmental regulation. Beginning in the 1970s, Congress and EPA began mandating that plants install the best available control technology (BAT) to reduce pollutants from industrial activity.<sup>48</sup> In the 1980s, scholars demonstrated that the unintended consequences of BAT-based environmental policy were particularly severe.<sup>49</sup> In the wake of this and similar critiques in

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46. See Cass R. Sunstein, *Behavioral Analysis of Law*, 64 U. CHI. L. REV. 1175, 1183 (1997) (citing a study finding that 90% of drivers considered themselves to be better than average).

47. But see Strahilevitz, *supra* note 40, at 1702–05.

48. Bruce A. Ackerman & Richard B. Stewart, *Reforming Environmental Law: The Democratic Case for Market Incentives*, 13 COLUM. J. ENVTL. L. 171, 173 (1988).

49. *Id.* at 173–75.

other areas, federal policy has moved increasingly toward outcome-based regulation in numerous regulatory areas.<sup>50</sup>

## 2. Outcome-Based Regulation

Outcome-based regulations, often known as performance standards, are the means by which governments directly target outcomes. In other words, “[a] performance standard specifies the outcome required, but leaves the specific measures [required] up to the discretion of the regulated entity.”<sup>51</sup> A classic example of a performance standard can be found in USDA’s biotechnology regulations. Rather than providing procedures for conducting field trials involving regulated genetically engineered plants,<sup>52</sup> the regulations provide simply: “The field trial must be conducted such that: (i) The regulated [plant] will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment.”<sup>53</sup>

Performance standards can have several advantages over traditional regulation. They permit regulated entities to choose the most efficient process or technology to meet a particular regulatory goal. They also promote the development and adoption of new technology. If a more efficient technology becomes available, a regulated party is free to switch to the new technology without waiting for the regulatory requirement to change. However, performance standards can be difficult to monitor, particularly when they seek to prevent a low-probability but severe-consequence outcome. In these cases, the best regulators can do is often to use an imperfect proxy for the severe-consequence outcome as a performance standard.<sup>54</sup> Performance standards can be expensive,

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50. See Cary Coglianese et al., *Performance-Based Regulations: Prospects and Limitations in Health, Safety, and Environmental Protection*, 55 ADMIN. L. REV. 705, 707 (2003) (noting some areas in which outcome-based regulation has been adopted). To be clear, traditional regulation is still very much an important part of federal regulatory programs.

51. *Id.* at 709.

52. Essentially all genetically engineered material is considered “regulated” until it is granted “nonregulated status” by USDA pursuant to 7 C.F.R. § 340.6 (2009).

53. 7 C.F.R. § 340.3(c)(5) (2009). The heading for § 340.3(c) is “Performance standards for introductions under the notification procedure.” Similar outcome-based requirements follow. See generally *id.* §§ 340.3(c)(1)–(6).

54. Coglianese et al., *supra* note 50, at 714–15.

particularly for small companies that might not have the resources to develop detailed procedures or new technologies on their own.<sup>55</sup>

### 3. *Tort Law*

Tort law is the traditional means by which states delegate the regulation of outcomes to private parties. Private parties who have suffered a negative outcome can sue—and in that suit seek to prove that a defendant behaved in a manner that satisfies the elements of a particular tort. A person who is harmed can sue on various grounds, such as negligence, strict liability, unreasonably dangerous activity, or false imprisonment. For each of these torts, a plaintiff must demonstrate a negative outcome in order to recover. The fact that someone is driving dangerously near me gives me no legal rights. He must create a negative outcome by running into me before I can sue.<sup>56</sup>

Of course, certain intentional torts may border on regulation of behavior, rather than outcomes. Assault, battery, and trespass to land give a plaintiff the right to sue when the outcome seems difficult to separate from the behavior at issue. However, these torts, which give an individual the ability to protect herself and her property, play a relatively minor role in the regulation of business and industrial activity.

### 4. *Delegated Regulation*

Delegated regulation conditions receipt of some type of state benefit on a prior decision by an entity to which the state has delegated authority.<sup>57</sup> Examples exist in various regulatory areas. The Securities

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55. *Id.* at 712.

56. Tort law also has at least one major disadvantage as a way of affecting ex ante incentives. To the extent that the effect of socially undesirable behaviors is spread among a large number of persons, there is a significant possibility no single person will find it worthwhile to sue. *See generally* Richard A. Epstein, *How To Create—or Destroy—Wealth in Real Property*, 58 ALA. L. REV. 741, 756 (2007). The two remedies for this are a class action suit or a lawsuit by the state using the same private-law mechanisms available to private actors. *Id.*

57. Delegated regulation is related to, but distinct from, the concept of gatekeeping. As developed in the corporate governance literature, gatekeepers are intermediaries—generally members of a profession—who perform one of two functions. First, they may be able to prevent a transaction by withholding their legally required certification. JOHN C. COFFEE JR., GATEKEEPERS: THE PROFESSIONS AND CORPORATE GOVERNANCE 2 (2006). Examples here include the attorney or auditor who must provide an opinion letter before a merger can go through. *Id.* Second, they may be repeat players who use their own reputational capital to “lend credibility to the subject company’s own disclosures or predictions.” *Id.* at 2–3. An example from the gatekeeping literature is the securities

and Exchange Commission (SEC) requires publicly traded companies to have accounting firms sign off on the companies' financial statements.<sup>58</sup> Most states delegate the process of accrediting law schools to the American Bar Association,<sup>59</sup> and the federal government relies on various accrediting bodies to determine whether particular educational institutions can receive federal financial aid.<sup>60</sup> USDA relies on both private entities and state agencies to certify that farms purporting to sell organic products comply with the requirements of the National Organic Program.<sup>61</sup> And—infamously in the post-2008 economic context—the SEC relies on the credit rating agencies to rate the creditworthiness of certain financial products.

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analyst. The analyst's approval does not fulfill any legal requirement but may affect a corporation's stock price or cost of capital. *Id.*

The key distinction between delegated regulation and gatekeeping is the focus of delegated regulation strategies on behaviors rather than outcomes. Many gatekeeping functions focus on an ultimate outcome or evaluation, and are enforced largely through tort liability. Do the company's financial statements accurately represent its financial position? Are the company's internal controls "adequate"? Has the company provided all material information to its prospective merger partner? Gatekeepers who fail to exercise the appropriate level of care in making these types of certifications are subject to professional liability suits if someone is harmed by the gatekeeper's error.

By contrast, a delegated regulation strategy seeks to target the relevant behaviors directly. A regulator might seek to rely on a gatekeeper in enforcing such a strategy—mandating that certain accounting procedures are used, that internal controls contain certain procedures, or that certain types of information are disclosed prior to mergers. To the extent most gatekeepers belong to self-regulating professional organizations, there will generally be elements of delegated regulation in most gatekeeper-based regulatory strategies. An example of an empirically significant delegated regulation entity that would not qualify as a simple gatekeeper is a securities industry self-regulatory organization (SRO) such as the Financial Institutions Regulatory Authority (FINRA) or the New York Stock Exchange (NYSE).

58. 15 U.S.C. § 77ff (2006) (requiring corporate boards to have accounts audited); *see also id.* § 77gg (2006) (requiring corporations to include auditors' reports in annual report).

59. States that do not require graduation from an ABA-accredited law school typically have their own programs for accrediting in-state schools that are not accredited by the ABA. *See, e.g.,* State Bar of California, Accredited Law School Rules, Rules 4.120–.121 (2009).

60. *See generally* 20 U.S.C. §§ 1002, 1099b, 1099c (2006).

61. *See generally* Organic Foods Production Act of 1990, 7 U.S.C. §§ 6501–6523 (2006 & Supp. II 2009); 7 C.F.R. §§ 205.400–.404 (2009).

## B. International Applications

These standard regulatory forms take on different characteristics when applied to foreign activity. All four types can apply extraterritorially but may present different problems when operating in a multinational context. The two publicly monitored regulatory forms, traditional regulation and outcome-based regulation, face both practical and political difficulties when applied to foreign activity. However, they both have the advantage that the government can avoid diplomatic problems by declining to pursue a particular enforcement action. Tort law, including private rights of action under federal statutes, relieves the government of monitoring responsibilities but permits private parties to initiate enforcement action. In areas ranging from the antitrust laws to the Alien Tort Claims Act, this private power to initiate extraterritorial enforcement actions has frequently led to diplomatic problems for the executive branch.<sup>62</sup>

With respect to delegated regulation, the addition of a third party between the government and the regulated foreign party may make it possible to regulate otherwise unreachable foreign behavior.<sup>63</sup> Traditional conceptions of sovereignty can make it very difficult for a government to take some actions in foreign territory. These same actions may raise less local concern if done by a private party or the government of that territory. To the extent this is the case, delegated regulation may have particular advantages in regulating foreign activity.

The incentive effects of delegated regulation depend heavily on whether the third party is a private entity or an agency of a foreign government. When the third party is a private entity, delegated regulation

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62. See, e.g., *F. Hoffmann-La Roche Ltd. v. Empagran S.A.*, 542 U.S. 155, 167–68 (2004) (discussing briefs filed by foreign governments objecting to private treble-damages actions under U.S. antitrust law); Curtis A. Bradley & Jack L. Goldsmith, *Rights Case Gone Wrong: A Ruling Imperils Firms and U.S. Diplomacy*, WASH. POST, Apr. 19, 2009, at A19 (discussing the potential impact of claims brought under the Alien Tort Statute on U.S. diplomacy); Kenneth W. Dam, *Extraterritoriality and Conflicts of Jurisdiction*, 77 AM. SOC'Y INT'L L. PROC. 370, 373 (1983) (speech by then-Deputy Secretary of State discussing foreign objections to private treble-damages actions under U.S. antitrust law).

63. Here, a cautionary note is in order. Delegated regulation is fundamentally different from international standard setting. In international standard setting, multiple national entities—some private, some public—come together to promulgate generally accepted international standards on a wide variety of issues. The most well-known example is the International Standards Organization. Although these entities' standards are frequently incorporated into national legislation, standard-setting organizations do not generally have any enforcement or monitoring role. A behavior-regulating rule based on an international standard can still be enforced through a regime of either public or third-party monitoring—it would accordingly fit into either the top-left or bottom-left quadrants of the diagram. See *supra* Part II.



begins to resemble franchise contracting.<sup>64</sup> The private entity has incentives to maximize revenue, and an effective regulatory scheme must be structured in a way that aligns the entity's private incentives with the public goals of the program. When the third party is an agency of a foreign government, it may also have an incentive to maximize revenue. However, it may be more difficult to alter the incentives of a foreign agency without affecting broader bilateral relations. Additionally, the foreign agency will naturally take direction from its own government.<sup>65</sup>

### III. THE CASE OF FOOD SAFETY

#### A. *Imported-Food Safety Regulation in the United States*

Responsibility for imported-food safety in the United States is split primarily between FDA and USDA's Food Safety and Inspection Service. USDA regulates most meat, poultry, and processed egg products; FDA is responsible for the safety of all other food sold in the United States.<sup>66</sup> State tort law is available to supplement the ex post aspects of the USDA and FDA regulatory programs.

#### 1. USDA

USDA's regulatory program contains significant ex ante and ex post components.<sup>67</sup> The ex ante aspect of the program relies on delegation to foreign government agencies; the ex post component involves direct inspection by USDA officials.

On the ex ante side, USDA-regulated meat and poultry products cannot be imported unless USDA has certified that the foreign country's inspection system ensures compliance with requirements "equivalent"<sup>68</sup>

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64. See *infra* note 169.

65. See *infra* Part V.C.

66. U.S. FOOD & DRUG ADMIN., *supra* note 1, at 4. More specifically, USDA is responsible for "the major red meat and poultry species and their products," with all remaining meat and poultry under the jurisdiction of FDA. GEOFFREY S. BECKER, CONG. RESEARCH SERV., U.S. FOOD AND AGRICULTURAL IMPORTS: SAFEGUARDS AND SELECTED ISSUES 6 n.17 (2008). With respect to eggs, USDA regulates processed egg products, while FDA regulates "most whole eggs." *Id.*

67. This may be possible in part because the agency has jurisdiction over a high-risk product area that is produced by a relatively limited number of establishments.

68. 9 C.F.R. § 327.2 (2009) (meat); *id.* § 381.196 (2009) (poultry); *id.* § 590.910 (2009) (egg products).

to those in place in the United States, and that “reliance can be placed upon”<sup>69</sup> certifications issued by that foreign country’s authorities. Because USDA requirements in place in the United States are quite intrusive, certifying a regulatory program as equivalent appears to require a relatively high level of ex ante regulation. As of this writing, USDA has certified approximately fifty countries to export meat products,<sup>70</sup> ten countries to export poultry products,<sup>71</sup> and two countries to export egg products.<sup>72</sup> China, which has been the focus of recent media attention related to FDA-regulated products, is not currently permitted to export USDA-regulated meat, poultry, or eggs to the United States.<sup>73</sup>

The ex post side of USDA’s regulatory program involves a relatively high rate of border inspections. The agency physically inspects about 10% of imported meat and poultry products.<sup>74</sup> These inspections include microbiological tests on samples from approximately 4% of meat and poultry imports.<sup>75</sup>

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69. 9 C.F.R. § 327.2 (meat); *id.* § 381.196 (poultry).

70. *See* 9 C.F.R. § 327.2(b) (listing countries eligible to export “the product of cattle, sheep, swine, and goats”). China is not on this list. Only four countries are eligible to export “the product of equines” to the United States. *See id.* § 327.2(c) (Argentina, Canada, New Zealand, and Paraguay).

71. *See* 9 C.F.R. § 381.196(b) (Australia, Canada, Chile, France, Great Britain, Hong Kong, Israel, Mexico, New Zealand, and People’s Republic of China). Of these, only six are eligible to export the full range of poultry products. Australia and New Zealand may export ratites only. *Id.* Mexico and China may export only processed poultry products slaughtered elsewhere, *id.* n.2, and China’s authorization to export processed poultry products is currently suspended. U.S. Dep’t of Agric., Food Safety & Inspection Serv., *Countries/Products Eligible for Export to the United States*, Dec. 11, 2009, [http://www.fsis.usda.gov/pdf/Countries\\_Products\\_Eligible\\_for\\_Export.pdf](http://www.fsis.usda.gov/pdf/Countries_Products_Eligible_for_Export.pdf); *see also* Bradley S. Klapper, *WTO Panel Probes U.S. Ban on Chinese Poultry*, WASH. POST, July 31, 2009.

72. 9 C.F.R. § 590.910 (Canada and Netherlands). The Netherlands’s authorization to export egg products to the United States is currently suspended. U.S. Dep’t of Agric., Food Safety & Inspection Serv., *supra* note 71.

73. *See supra* notes 70–72.

74. BECKER, *supra* note 66, at 7 (citing *Hearing To Review Recent Recalls in the Meat Industry Before the Subcomm. on Livestock, Dairy, and Poultry of the H. Comm. on Agriculture*, 110th Cong. 6–34 (2007) (statement of Dr. Richard Raymond, Under Secretary for Food Safety, Food Safety & Inspection Service, U.S. Department of Agriculture, Washington, D.C.), *available at* <http://agriculture.house.gov/testimony/110/110-35.pdf>).

75. *Id.* at 30.

## 2. FDA

FDA's imported-food safety program relies primarily on ex post measures. Ex ante regulatory requirements exist, but enforcement resources are focused heavily on ex post measures.

Two contrasts with USDA's program are particularly important. First, FDA does not require prior approval of a country's regulatory regime before that country can export food products it produces to the United States. Second, FDA's border inspection rate is much lower than USDA's.

On the ex ante side, the Federal Food, Drug, and Cosmetic Act (FFDCA) has long required that imported foods be produced, processed, and stored under the same sanitary conditions required for domestically produced food.<sup>76</sup> Yet despite the recent implementation of registration and recordkeeping requirements for foreign facilities,<sup>77</sup> enforcement is extremely limited. Although there has apparently been some double counting,<sup>78</sup> FDA has asserted that it has approximately 189,000 registered foreign facilities that "manufacture, process, pack, or hold food consumed by Americans."<sup>79</sup> Between 2001 and 2007, FDA inspected only 1034

76. See GEOFFREY S. BECKER & HAROLD F. UPTON, CONG. RESEARCH SERV., SEAFOOD SAFETY: BACKGROUND AND ISSUES 2 (2009) (asserting that FDA "requires that all domestic and foreign food manufacturing facilities adhere to Good Manufacturing Practices") (citing 21 C.F.R. pt. 110 (2009)), available at <http://www.nationalaglawcenter.org/assets/crs/RS22797.pdf>. See generally 21 U.S.C. § 331(a) (2006) (prohibiting the introduction of "adulterated" food into interstate commerce); *id.* § 342(a)(4) (2006) ("A food shall be deemed to be adulterated . . . if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health . . .").

77. FDA began requiring registration of foreign food production facilities in 2003, in compliance with the Bioterrorism Preparedness and Response Act of 2002. See 21 C.F.R. §§ 1.225–1.243 (2009). See generally Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 58,894 (Oct. 10, 2003). Also in compliance with the 2002 Act, FDA promulgated extensive recordkeeping requirements for foreign facilities in 2004. See 21 C.F.R. § 1.326(a) (2009). See generally Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 69 Fed. Reg. 71,562 (Dec. 9, 2004).

78. BECKER, *supra* note 66, at 4 n.8 (noting that 189,000 figure in FDA's Food Protection Plan "[is] inflated, because facilities engaged in more than one activity [e.g., manufacturing, processing, packaging, or holding food] are counted multiple times").

79. U.S. FOOD & DRUG ADMIN., *supra* note 1, at 6. FDA estimates that an inspection of one of these facilities would cost the agency \$16,700. LISA SHAMES, GOV'T ACCOUNTABILITY OFFICE, FEDERAL OVERSIGHT OF FOOD SAFETY: FDA HAS PROVIDED

facilities in fifty-four countries.<sup>80</sup> This included a total of only 33 facility inspections in China, 30 facility inspections in India, and 104 facility inspections in Mexico.<sup>81</sup> FDA did not inspect a single Chinese facility in 2001, 2006, or 2007.<sup>82</sup>

Instead, FDA relies almost entirely on ex post measures to ensure the safety of imported food. FDA's primary ex post power is the authority to refuse admission to foods offered for import into the United States.<sup>83</sup> FDA may request samples of food products offered for import and may refuse admission when it appears that the sample has been "manufactured, processed, or packed under insanitary conditions," or is adulterated, misbranded, or otherwise not permitted to be introduced into the United States.<sup>84</sup>

In most circumstances, the possibility of border inspection is almost all there is to FDA import regulation. Because of the high volume of imported food products, only a small proportion of them can be sampled at the border. FDA inspects only about 1% of food shipments,<sup>85</sup> using risk analysis techniques to focus its inspections on high-risk product categories and manufacturers with a history of violating import regulations.<sup>86</sup>

## *B. Market Failure*

### *1. The Case for Ex Ante Regulation*

For domestically produced food, the United States has long relied on a combination of traditional regulation and tort liability. In most cases, the primary type of tort liability applied to foods that actually cause

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FEW DETAILS ON THE RESOURCES AND STRATEGIES NEEDED TO IMPLEMENT ITS FOOD PROTECTION PLAN 8 (2008). The total cost to inspect each foreign facility once would be \$3.16 billion. *Id.*

80. SHAMES, *supra* note 79, app. I.

81. *Id.*

82. *Id.*

83. 21 U.S.C. § 381(a) (2006 & Supp. I 2007).

84. *Id.*

85. JEAN C. BUSBY ET AL., U.S. DEP'T OF AGRIC., FOOD SAFETY AND IMPORTS: AN ANALYSIS OF FDA FOOD-RELATED IMPORT REFUSAL REPORTS 6 (2008) (citing ROBERT A. ROBINSON, GOV'T ACCOUNTABILITY OFFICE, FOOD SAFETY AND SECURITY: FUNDAMENTAL CHANGES NEEDED TO ENSURE SAFE FOOD 7 (2001)).

86. BUSBY ET AL., *supra* note 85, at iii. The inspection percentage is still low in high-risk product categories. For example, FDA sampled around 2% of seafood shipments between 2003 and 2006. *Id.* at 6 (citing FOOD & WATER WATCH, *supra* note 16, at 7).

harm is strict product liability.<sup>87</sup> Compensatory damages are generally available and should equal at least the amount of harm caused by the food. Punitive damages are available in situations where the defendant's conduct can be shown to be outrageous, reckless, or malicious.<sup>88</sup> Traditional regulation complements, but does not replace, this aggressive tort liability regime.

The economic case for government regulation of food production is relatively straightforward.<sup>89</sup> Food safety presents an information problem. Consumers cannot readily distinguish *ex ante* between safe or unsafe food, and have some trouble identifying unsafe food *ex post*.<sup>90</sup> This information problem diminishes the incentive effects of both market pricing and tort liability. With respect to market pricing, producers of safe food are unable to capture a price premium for this characteristic. They may be able to obtain a price premium for other characteristics that serve as a proxy for food safety—organic status is one example—but safety itself cannot be credibly communicated to the consumer.<sup>91</sup>

This information problem also reduces the incentive effects of tort liability. With the exception of a few identifiable illnesses, such as *E. coli* and hepatitis A, that are sufficiently severe to capture the attention of food safety authorities, consumers can rarely establish with any

87. See generally RESTATEMENT (SECOND) OF TORTS § 402A (1965); RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 1 (1998). Indeed, food that causes harm is often considered a classic case of a situation where strict liability is appropriate.

88. See generally RESTATEMENT (SECOND) OF TORTS § 908 (1979). In some circumstances, courts have permitted juries to award punitive damages even on strict product liability claims. See *Acosta v. Honda Motor Co.*, 717 F.2d 828, 833 & n.6 (3d Cir. 1983) (collecting cases).

89. The incentives associated with food safety regulation are very different from those associated with prescription drug regulation for a simple reason: FDA is not asked to weigh the benefits and risks of a turnip or a candy bar before it can be sold. This means that the agency does not have an incentive to overweigh the potential harm versus the potential benefit based on the fear that it will suffer a political backlash anytime a food product's inherent risks result in harm in some consumers. On the very different incentive structures that apply to FDA premarket approval of prescription drugs, see RICHARD A. EPSTEIN, *OVERDOSE: HOW EXCESSIVE GOVERNMENT REGULATION STIFLES PHARMACEUTICAL INNOVATION* 116–18 (2006) (noting FDA incentives to overweigh risks of allowing drugs on the market and underweigh risks of keeping drugs off the market).

90. Lorraine Mitchell, *Economic Theory and Conceptual Relationships Between Food Safety and International Trade*, in *INTERNATIONAL TRADE AND FOOD SAFETY: ECONOMIC THEORY AND CASE STUDIES*, *supra* note 13, at 10–12.

91. Cf. George Akerlof, *The Market for "Lemons": Qualitative Uncertainty and the Market Mechanism*, 84 Q.J. ECON. 488 (1970).

degree of certainty which of several food items they ate on a particular day made them sick. This means that consumers are frequently unable to assign blame *ex post* for unsafe food.<sup>92</sup> Moreover, even in cases when consumers are able to assign blame, it is difficult for them to recover in a tort action against a domestic producer.<sup>93</sup>

This information problem is compounded by the fact that many food products—whether produced domestically or abroad—are sold as unbranded or weakly branded products in the United States. Examples include fresh fruits, vegetables, and seafood, in which consumer choices appear to be influenced more by perceivable product characteristics than by the identity of the producing company. Without strong brand association, fresh food producers are less likely to internalize the costs of safety problems than brand-driven companies selling drugs, processed foods, or consumer products.<sup>94</sup>

Even if consumers were able to identify and sanction producers of unsafe food, this would be unlikely to produce a socially optimal level of food safety. The reason for this is simple. Foodborne illnesses create externalities, so consumers do not suffer all of the harm associated with unsafe food. The most easily identifiable externalities are lost workdays, resources spent on medical care, and time devoted to care of the sick person by friends and relatives.<sup>95</sup> Accordingly, a combination of market

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92. Mitchell, *supra* note 90, at 10, 12.

93. *Id.* at 15 (citing JEAN C. BUZBY ET AL., U.S. DEP'T OF AGRIC., PRODUCT LIABILITY AND MICROBIAL FOODBORNE ILLNESS 15 (2001), *available at* <http://www.ers.usda.gov/publications/aer799/aer799.pdf> (reporting that, over the ten-year period studied, consumers won only one-third of jury trials in food poisoning cases)).

94. Grocery store chains have diversified product lines, so public outcry against a particular product may not represent the same threat to future revenue as loss of public confidence in a key brand. The consuming public appears to accept that grocery stores—and to some degree, restaurants—do not have control over their entire supply chains. In a relatively sophisticated manner, consumers harshly penalize companies whose food safety problems are shown to result at least in part from their own internal procedures. However, consumers appear to be more lenient with grocery stores that sell products contaminated earlier in the supply chain. *Compare Business Brief: Foodmaker Sees Loss For Fiscal 2nd Period Related to Illnesses*, WALL ST. J., Mar. 25, 1993, at B4 (discussing short-term fallout of *e. coli* crisis at Jack in the Box restaurants), and Mark Veverka, *Savvy Helps Jack in the Box Weather Crisis*, WALL ST. J., Aug. 6, 1997, at CA1 (discussing longer-term implications of *e. coli* crisis on parent company of Jack in the Box restaurants) with FOOD MARKETING INSTITUTE, U.S. GROCERY SHOPPER TRENDS: 2009 94-98, 100 (2009) (reporting study results indicating that, despite a 2009 outbreak involving nuts sold in grocery stores, consumer confidence in the safety level of grocery stores was “still much higher than the trust consumers place in safety at restaurants”).

95. Mitchell, *supra* note 90, at 12.

sanctions and tort law is likely to result in a level of food safety below the socially optimal level.<sup>96</sup>

For imported food, the information problems that reduce the effectiveness of market mechanisms and tort liability systems continue to apply. Additionally, multinational cases present two additional problems that further reduce the incentive effects of tort liability.

First, legal rules make it far more difficult to recover from a foreign company in a tort suit than from a comparable domestic company. These rules include personal jurisdiction and evidentiary requirements that have a disparate impact on cases with foreign elements. Personal jurisdiction requirements are standards rather than rules, so their effect is difficult to predict in any individual case. However, they do permit courts to conclude that they lack jurisdiction over foreign defendants with insufficient connections to the United States.<sup>97</sup> Because U.S. producers can always be sued in at least one state, there is an element of jurisdictional uncertainty to suits against foreign producers that does not exist in comparable domestic cases. Moreover, even when jurisdiction can be obtained, foreign defendants may be able to take advantage of protective local regulatory structures to disappear, perhaps transferring their assets to another entity or reincorporating under another name.<sup>98</sup>

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96. To whatever extent punitive damages make up for this in the domestic context, they are likely to be less effective with respect to food produced abroad. The same jurisdictional and evidentiary hurdles that make it difficult to get a judgment against a foreign defendant will also reduce the degree to which the threat of punitive damages affects foreign incentives. Moreover, many foreign states assert a public policy against punitive damages and may make it exceptionally difficult to gather evidence for any case in which punitive damages are a risk.

97. Personal jurisdiction case law suggests that foreign defendants in civil litigation have two significant defenses to jurisdiction under the Fourteenth Amendment Due Process Clause. First, foreign defendants may not be subject to personal jurisdiction if they did not take actions "purposefully directed" toward the United States. *See Asahi Metal Indus. Co. v. Superior Court of Cal.*, 480 U.S. 102, 112 (1987) (O'Connor, J., plurality opinion). Second, sufficiently attenuated connections between the defendant and the United States may make jurisdiction "unreasonable[.]" *id.* at 114 (majority opinion), such that it "offend[s] traditional notions of fair play and substantial justice," *id.* at 113 (internal quotations omitted). *Cf. Lea Brilmayer & Charles Norchi, Federal Extraterritoriality and Fifth Amendment Due Process*, 105 HARV. L. REV. 1217, 1219-23 (1992) (suggesting that the Fifth Amendment Due Process Clause may make similar defenses available to defendants faced with extraterritorial application of federal law).

98. *Cf. Don Lee & Abigail Goldman, Factory Linked to Tainted Pet Food Found Closed*, SEATTLE TIMES, May 11, 2007, at A12 (stating that Chinese factory linked to 2007 pet food scandal was bulldozed by its owner days before FDA investigators arrived); U.S. Food & Drug Admin., Transcript of FDA Press Conference on Contaminated

Similarly, evidentiary rules limit the conditions under which foreign evidence can be admitted in U.S. courts. These rules impose costs and procedural requirements not applicable in the domestic context.<sup>99</sup> Given these hurdles, a rational plaintiff will require a higher expected recovery<sup>100</sup> to bring a case against a foreign producer than against a U.S. producer.<sup>101</sup>

Second, the social and environmental context in many exporting countries increases the likelihood that imported food will present safety concerns. As recent events in China indicate, nascent business norms in developing countries may not be sufficient to prevent intentional adulteration of a type that is much rarer in brand-conscious—and in the case of the United States, litigious—developed countries.<sup>102</sup> Rapid industrial development has left many areas of developing countries with unclean water and contaminated soil.<sup>103</sup> To the extent food safety and environmental regulations exist in developing countries, they are less likely to be enforced. Moreover, many developing countries have rampant corruption problems, and it may be economically rational, at least in the short term, for producers to pay bribes rather than comply with more expensive regulations. These corruption problems are compounded when

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Animal Feed (May 10, 2007) (statement of Walter Batts, Deputy Director of the Office of International Programs), *available at* <http://www.fda.gov/downloads/NewsEvents/Newsroom/MediaTranscripts/UCM123611.pdf> (indicating that two Chinese facilities FDA visited had been “closed down” and had their “machinery dismantled” before FDA investigators arrived).

99. *See, e.g.*, 28 U.S.C. § 1781 (2006) (transmittal of letter rogatory or request); *id.* § 1783 (2006) (subpoena of person in foreign country); FED. R. EVID. 902(3) (authentication of foreign public documents); FED. R. CIV. P. 28(b) (depositions in foreign countries); Convention on the Taking of Evidence Abroad in Civil or Commercial Matters, Mar. 18, 1970, 23 U.S.T. 2555, 847 U.N.T.S. 231. *See generally* GARY BORN & PETER RUTLEDGE, INTERNATIONAL CIVIL LITIGATION IN U.S. COURTS 907–1007 (4th ed. 2007) (discussing the special problems associated with obtaining evidence abroad for use in U.S. court).

100. By expected recovery, I mean simply the value of the potential award multiplied by the likelihood of recovery.

101. The procedural difficulties involved in suing foreign manufacturers alter manufacturer incentives much the way that nineteenth-century privity requirements did. *Compare* *Winterbottom v. Wright*, (1842) 152 Eng. Rep. 402, 404–05 (Exch. Div.) (applying privity requirement to hold that coach manufacturer was not liable to coach driver with whom he had not directly done business), *with* *MacPherson v. Buick Motor Co.*, 111 N.E. 1050, 1053–55 (N.Y. 1916) (abandoning privity requirement and discussing effects of change on manufacturer incentives).

102. *See supra* text accompanying notes 9–11 (discussing milk adulteration).

103. Of course, these areas exist in developed countries as well. However, in developed countries they are more likely to have been identified and either blocked from use in food production or subjected to cleanup programs.



they interact with domestic governance structures that tie the evaluation of regional officials to the rate of economic growth in their region.<sup>104</sup>

## 2. Discriminatory Regulation

Together, the information problems associated with food safety, the legal rules applicable to international litigation, and the social and environmental context in food-exporting countries suggest that a combination of market incentives and tort law does not guarantee a socially optimal level of safety for imported food. One possible way to correct this market failure is through ex ante regulation; another option is ex post liability. Part IV, below, examines three potential approaches to ex ante regulation. The ex post option has been developed in detail elsewhere<sup>105</sup> and will not be a primary focus of the discussion below.

To address the ex post option briefly, a recent article suggests that the way to correct market failures associated with imported products is to impose strict liability and heightened penalties on U.S. importers, forcing them to “act as *de facto* regulators” of foreign production processes.<sup>106</sup> Although this proposal could increase the safety of imported products, it also appears to raise several concerns.

First, a regime of strict liability and heightened penalties appears to face its own information problem. It is difficult to know how a regulatory agency could determine in advance the appropriate penalty to deter safety violations. If a single enhanced penalty regime, like treble damages, were applied to all foreign production, it would almost certainly overregulate in certain areas and underregulate in others. This could perhaps be ameliorated by moving to individual penalty regimes for particular product sectors or even individual products, but with each

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104. See Daniel Abebe & Jonathan S. Masur, *International Agreements, Internal Heterogeneity, and Climate Change: The “Two Chinas” Problem*, 50 VA. J. INT’L L. 325, 351 (2010) (noting that “local officials [in China] are evaluated primarily on their ability to deliver sustained economic growth”). This type of incentive structure will obviously be a disincentive to enforcing regulations that interfere with economic growth.

105. Bamberger & Guzman, *supra* note 34, at 1411–13; see also Tom Baker, *Bonded Import Safety Warranties*, in IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY 215, 216–24 (Cary Coglianese et al. eds., 2009); Kenneth A. Bamberger & Andrew T. Guzman, *Importers as Regulators: Product Safety in a Globalized World*, in IMPORT SAFETY: REGULATORY GOVERNANCE IN THE GLOBAL ECONOMY, *supra*, at 193, 195–96 [hereinafter Bamberger & Guzman, *Importers as Regulators*].

106. Bamberger & Guzman, *supra* note 34, at 1409.

increase in specificity the approach would bear an increasing resemblance to tariff schedules. Whether set by statute or regulation, these penalty schedules would, like tariffs themselves, be subject to short-term political meddling and protectionist impulses. Moreover, their functional similarity to tariffs would likely pose a significant risk of successful WTO challenges.<sup>107</sup>

Second, a regime of strict liability and heightened penalties is likely to shift resources inefficiently to domestic production. Food is a product category in which risks can be mitigated but not removed. Under a strict liability/heightened penalty approach, a domestic firm can choose between buying domestically produced green onions and facing standard tort liability or buying foreign-produced green onions and facing heightened penalties. Even if the foreign green onions can be produced more cheaply at a given level of safety, the firm will choose to purchase domestic green onions because its downside risks are much lower if a problem does occur. This result will help domestic green onion growers but will result in a deadweight social loss.

Third, moving to a strict liability/heightened penalty regime would likely result in a radical restructuring of the domestic import industry. Heightened penalties would make it more difficult for small importers to operate, and they would be forced either to combine into larger entities or purchase insurance against the penalties.<sup>108</sup> Insurance companies might develop their own ways of rating the risk of particular producers or regions.<sup>109</sup> Although this type of industry restructuring is not necessarily bad, it is a significant change that could have unexpected ramifications.

Fourth, a strict liability/heightened penalty regime will still need to overcome the basic information problem of ex post regulation. Unless an importing firm or insurance company knows for which potential contaminants to test, it will be forced to find some way to conduct its own ex ante regulation of production processes overseas.<sup>110</sup> This may result in the creation of private entities similar in function to those that would be created under a delegated regulation strategy.<sup>111</sup> However, the

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107. *But see id.* at 1439–42 (arguing that a regime of strict liability and heightened penalties would survive WTO scrutiny because it is necessary to protect a vital state interest in safety regulation and is the least restrictive alternative available). On the relationship between WTO rules and safety regulation, see *infra* Part VI.

108. *See Baker, supra* note 105, at 229–30l; Bamberger & Guzman, *supra* note 34, at 1433 (discussing possible role of insurance industry); Bamberger & Guzman, *Importers as Regulators*, *supra* note 105, at 205.

109. *See Baker, supra* note 105, at 229–30.

110. *See supra* Part III.B.1.

111. *See Bamberger & Guzman, supra* note 34, at 1433.

more circuitous route that a strict liability/heightened penalty regime uses to reach this result may introduce the possibility for additional market failures.

Overall, strict liability and heightened penalties is one potential approach to import safety problems. However, it raises its own concerns— and it may be less likely to survive WTO challenges than some ex ante strategies.

#### IV. REGULATING BEHAVIORS ABROAD

##### A. *Three Regulatory Strategies*

To the extent a country seeks to include an ex ante component in its regulation of foreign-produced goods, there are three basic strategies for regulatory enforcement: (1) direct extraterritorial regulation; (2) delegation to a foreign government agency; and (3) delegation to a domestic or foreign private entity. All three of these strategies play a significant role in the food safety bills currently under consideration in the U.S. Congress.

##### 1. *Direct Extraterritorial Regulation*

Direct extraterritorial regulation involves direct employment of inspectors by the government of the importing country. This could either mean hiring citizens of the importing country or some third country and sending them to the exporting country, or hiring citizens of the exporting country to work in their homeland. As discussed further in Part V.A, the characteristics of the direct regulatory program may vary significantly between these options.

##### 2. *Delegation to a Private Entity*

Delegation to a private entity involves a government decision to require some type of certification by a private entity as a condition to market entry. This approach requires the regulating government to develop a program to accredit and supervise third-party certifiers. In essence, the government chooses to focus its attention on a group of private regulators rather than on the regulated industry itself. As a matter of institutional design, the basic feature of delegation to a private entity is a change from a principal-agent relationship between government and on-the-ground regulator to a principal-agent-subagent relationship between government, private entity, and on-the-ground regulator.

### 3. *Delegation to a Foreign Government Agency*

Delegation to a foreign government agency involves a government decision to rely explicitly on a foreign government's regulatory structure. This can involve either formal finding of equivalence—USDA's approach to meat, egg, and poultry imports—or a requirement that the exporting country certify that particular export shipments (or exports from certain companies, industries, or regions) meet regulatory requirements in the importing country. As a matter of institutional design, the basic feature of delegation to a foreign government agency is a principal-*double agent*-subagent relationship between the importing government, the foreign agency and the on-the-ground regulator. As discussed further in Part V.C, the fact that the foreign government agency has a second principal—its political superiors in the foreign government—can introduce significant complications for this regulatory strategy.

#### *B. Two Pending Bills*

As of this writing, Congress is considering two versions of a major food safety bill. The U.S. House of Representatives passed H.R. 2749, the Food Safety Enhancement Act of 2009, in July 2009.<sup>112</sup> The U.S. Senate Committee on Health, Education, Labor, and Pensions reported S. 510, the FDA Food Safety Modernization Act, to the full Senate in November 2009.<sup>113</sup> The Senate, which has been focused on health care reform,<sup>114</sup> has—as of this writing—yet to act on S. 510. However, the bills appear to have broad congressional and administration support. It is not unrealistic to anticipate that a major food safety law could be passed by Congress and signed by the President during the 111th Congress.<sup>115</sup>

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112. See Food Safety Enhancement Act of 2009, H.R. 2749, 111th Cong. (2009), available at <http://www.govtrack.us/congress/bill.xpd?bill=h111-2749> (last visited May 18, 2010).

113. See FDA Food Safety Modernization Act, S. 510, 111th Cong. (2009), available at <http://www.govtrack.us/congress/bill.xpd?bill=s111-510> (last visited May 18, 2010).

114. See generally Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029.

115. High profile reports of safety problems with both domestic and imported food products have galvanized public opinion, with much of the attention focused on safety issues in products produced in China. Outside the United States, the sheer scope of harm caused by contaminated infant formula in China—nearly 300,000 persons sickened, over 50,000 hospitalized—has served as a stark reminder that harm from adulterated food is not necessarily limited to tens or hundreds of people. MORRISON, *supra* note 6, at 10 (citing Chinese government reports of 51,900 people hospitalized); cf. NASSIM NICHOLAS

Both bills rely on all three of the ex ante regulatory strategies discussed above. Provisions increasing U.S. reliance on direct extraterritorial regulation include those providing for explicit extraterritorial application of the FFDCA,<sup>116</sup> a dedicated foreign inspectorate,<sup>117</sup> annual or biennial registration of foreign food facilities,<sup>118</sup> direct inspection of foreign facilities,<sup>119</sup> refusal of imports from facilities that refuse or delay inspection,<sup>120</sup> foreign FDA offices,<sup>121</sup> enhanced access to records,<sup>122</sup> and broad subpoena authority.<sup>123</sup>

Provisions increasing U.S. reliance on delegation to domestic and foreign private entities include those providing for mandatory registration of importers,<sup>124</sup> mandatory registration of customs brokers,<sup>125</sup> mandatory importer verification of their suppliers' compliance with U.S. food safety laws,<sup>126</sup> accreditation of private entities to certify compliance with U.S. food safety laws,<sup>127</sup> and expedited processing for importers who demonstrate enhanced control over their supply chains.<sup>128</sup>

Provisions increasing U.S. reliance on delegation to a foreign government agency include those providing for foreign government inspections to satisfy risk-based inspection schedules,<sup>129</sup> FDA determination of whether foreign regulatory systems can provide assurances of safety levels equivalent to the U.S. system,<sup>130</sup> and accreditation of foreign

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TALEB, *THE BLACK SWAN: THE IMPACT OF THE HIGHLY IMPROBABLE*, at xvii–xxiv (2007) (arguing that unexpected events and extreme outlier situations drive history); Daniel A. Farber, *Uncertainty* 19–23 (Univ. of Cal., Berkeley, Public Law Research Paper No. 1555343), available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1555343](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1555343) (discussing the policy implications of probability distributions where “tail thickness” is uncertain). Public opinion polls report decreasing trust in the safety of the nation’s food supply, and a heavily Democratic Congress appears ready to move in a more proregulatory direction on consumer safety issues.

116. H.R. 2749, 111th Cong. § 312 (2009).

117. *Id.* § 208.

118. *Id.* § 101; S. 510, 111th Cong. § 102 (2009).

119. H.R. 2749 § 207; S. 510 § 307.

120. H.R. 2749 § 207.

121. S. 510 § 309.

122. H.R. 2749 § 106.

123. *Id.* § 211.

124. *Id.* § 204.

125. *Id.* § 205.

126. S. 510 § 301.

127. H.R. 2749 § 109; S. 510 § 308.

128. H.R. 2749 § 113; S. 510 § 302.

129. H.R. 2749 § 105.

130. S. 510 § 305.

government agencies to certify compliance with U.S. food safety laws.<sup>131</sup>

Other provisions require FDA to set standards that could be enforced under one or more of the three regulatory strategies. These include promulgation of performance standards for particular foods or food categories,<sup>132</sup> promulgation of safety standards for produce and certain other agricultural products,<sup>133</sup> mandatory implementation of management-based regulatory programs,<sup>134</sup> mandatory risk-based facility inspection schedules,<sup>135</sup> traceability requirements,<sup>136</sup> country-of-origin labeling,<sup>137</sup> and promulgation of regulations for good importer practices.<sup>138</sup>

### *C. Three Principal-Agent Problems*

Principal-agent problems are a fundamental part of government activity. The incentives of the agent, the government employee, will rarely align perfectly with those of his or her ultimate principal, the ordinary citizen. However, principal-agent problems have a special relevance for efforts to regulate foreign activity—where agency problems are presented that go beyond those in an equivalent domestic regulatory situation.

#### *1. The Regulatory License Problem*

In his work on the credit ratings industry, Professor Frank Partnoy has proposed the “regulatory license” as a way of understanding the consequences of giving legal effect to the ratings decisions of a private entity.<sup>139</sup> When its rating does not have a legal effect, the ability of a private agency to make money rests on its “reputational capital.”<sup>140</sup> The agency must cultivate a reputation for reliable, accurate ratings in order to survive. Classic examples of ratings entities that survive at least in

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131. H.R. 2749 § 109; S. 510 § 308.

132. H.R. 2749 § 103; S. 510 § 104.

133. H.R. 2749 § 104; S. 510 § 105.

134. H.R. 2749 § 102; S. 510 §§ 103, 106. Examples of management-based regulatory programs include hazard analysis, preventative controls, and food defense programs, as well as associated recordkeeping requirements. H.R. 2749 § 102; S. 510 §§ 103, 106.

135. H.R. 2749 § 105.

136. *Id.* § 107; S. 510 §§ 204–205.

137. H.R. 2749 § 202.

138. *Id.* § 204.

139. See generally Frank Partnoy, *The Siskel and Ebert of Financial Markets?: Two Thumbs Down for the Credit Ratings Agencies*, 77 WASH. U. L.Q. 619, 682–86 (1999).

140. *Id.* at 682.

part on reputational capital are Consumer Union, which publishes *Consumer Reports* magazine,<sup>141</sup> and *Good Housekeeping*, which confers the Good Housekeeping Seal of Approval.<sup>142</sup>

However, once the ratings of a private entity or other third party are given legal effect, the incentives facing that entity change. The entity is in effect selling a license to participate in the market. Although it previously had the incentive to keep its reputation high, it now has the incentive to maximize profit so long as it does not lose its right to sell the regulatory license.<sup>143</sup> This type of profit maximization may lead the entity to take reputation-reducing actions—such as issuing poor quality ratings—that it would not take if it relied solely on its reputational capital to justify its fees.<sup>144</sup>

At a macro level, regulatory license analysis suggests that the more important a private entity's regulatory role becomes, the more it will face incentives to maximize profit or revenue at the expense of high quality decisions. This in turn means governments choosing to rely on third-party monitoring will need to devote additional resources to “watching the watchdogs.” This, of course, limits the benefits of relying on delegated authority in the first place.

## 2. Interest Group Capture

The addition of a separate entity between the government and the on-the-ground regulator presents an additional set of interest group capture problems. In any regulatory situation, there is a risk that private interests may capture the relevant government agency. However, inserting a private entity as a middleman effectively gives the regulated industry an additional opportunity to capture its regulator.

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141. *See id.* at 685.

142. Both of these entities also survive, in part, on magazine subscriptions; Consumers Union also accepts donations. *See generally* Consumers Union, About Us, <http://www.consumerreports.org/cro/aboutus/mission/overview/index.htm> (last visited May 18, 2010). But the viability of both magazines and the ability of Consumers Union to collect donations rest on reputational capital.

143. Partnoy, *supra* note 139, at 684.

144. *Id.* If that entity is a for-profit entity, it will be incentivized to conduct its regulatory functions so as to maximize its own profits rather than social welfare. If the entity is a nonprofit organization, it will still have incentives to maximize revenue, which it can then distribute to its own leadership through salaries and perks.

In particular, there is a risk anytime the targets of regulations are paying, either directly or indirectly, for the privilege of being inspected. The effects of these payments will vary based on the manner in which they are assessed.<sup>145</sup> However, some general observations can be made. First, any entity—public or private—will seek to spend less money per inspection than it receives in fees for that inspection. If fees are set by the government at below cost, inspection quality will go down to the level that can be justified by the fees generated.

Second, there is a risk that the inspection entity will adopt a “[he] who pays the piper calls the tune”<sup>146</sup> approach and begin to see the subject of regulation, rather than the government agency responsible for supervising the inspection entity, as its “principal.” This is obviously a risk with private for-profit entities and may also be a problem with nonprofit entities and foreign government agencies.<sup>147</sup> However, the “piper” problem is almost certain to be more severe in situations in which regulated parties have a choice among regulators.<sup>148</sup> For example, it appears that competition for business among credit rating agencies played at least some role in the ratings decisions those agencies issued.<sup>149</sup>

### 3. *Bribery and Threats of Violence*

Bribery is a tremendous problem in many food-exporting countries. For example, Mexico, China, and Thailand are the second, third, and fourth largest suppliers of agricultural and seafood imports to the United

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145. They could, for example, be assessed per inspection, per facility over  $X$  time period, or by quantity or monetary value of goods inspected.

146. See generally OXFORD ENGLISH DICTIONARY ONLINE (2010), <http://dictionary.oed.com> (enter “piper,” and click “Find Word”) (last visited Apr. 27, 2010) (“[W]ho pays the piper calls the tune . . . : whoever pays the cost of an activity [or] undertaking . . . has control over it.”).

147. Nonprofit entities are not immune to self-dealing risks. One high profile example is the massive pay package and perks Richard Grasso received as head of the then-nonprofit New York Stock Exchange. See *Grasso’s Big Board: How To Make Money on the Stock Exchange*, ECONOMIST, Jan. 20, 2007, at 2.

148. Similar phenomena have been observed in situations where parties have a choice among adjudicators. Cf. YVES DEZALAY & BRYANT G. GARTH, DEALING IN VIRTUE: INTERNATIONAL COMMERCIAL ARBITRATION AND THE CONSTRUCTION OF A TRANSNATIONAL LEGAL ORDER 33 (1996) (arguing that international arbitrators compete for business by cultivating a reputation for a certain type of “virtue”); JOHN H. LANGBEIN ET AL, HISTORY OF THE COMMON LAW: THE DEVELOPMENT OF ANGLO-AMERICAN LEGAL INSTITUTIONS 250 (2009) (discussing competition for business among the English courts between the fifteenth and seventeenth centuries).

149. See *infra* note 168.



States.<sup>150</sup> Transparency International considers all of these to be countries with a “serious corruption problem in the public sector,”<sup>151</sup> and anecdotal reports of routine bribery in these countries are common. This suggests that a major source of principal-agent problems will be the ability of supervisors to prevent bribe taking by inspectors in the field.

The flip side of the bribery problem is the threat that nonfavorable inspection outcomes will result in harm to the inspector and those close to the inspector. This principal-agent problem is also endemic to many food-exporting countries and has the same structure as the bribery problem. The primary distinction is that self-dealing by the agent is used to prevent losses rather than achieve gains. In practice, the two may occur together—“accept this money or I’ll break your kneecaps.”

## V. APPLICATION

### A. *Direct Extraterritorial Regulation*

#### 1. *Principal-Agent Problems*

One direction for reform efforts is direct extraterritorial regulation—traditional regulation applied abroad. Direct regulation largely eliminates the regulatory license problem, at least from the perspective of the regulating government, because no separate entity is given the right to “sell” a license to participate in the market. It also involves less interest group capture risk than the alternative regulatory strategies. Although it remains possible to capture the regulating agency in the importing

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150. BECKER, *supra* note 66, at 2 tbl.1. Canada, a country with fewer corruption problems, is the largest supplier. *Id.*

151. Transparency Int’l, *2008 Corruption Perceptions Index: Regional Highlights: Asia-Pacific*, [http://www.transparency.org/layout/set/print/policy\\_research/surveys\\_indices/cpi/2008/regional\\_highlights\\_factsheets](http://www.transparency.org/layout/set/print/policy_research/surveys_indices/cpi/2008/regional_highlights_factsheets) (noting that a score “below 5” indicates “a serious corruption problem in the public sector”); *see also* Transparency Int’l, *2008 Corruption Perceptions Index: Regional Highlights: Americas*, [http://www.transparency.org/layout/set/print/policy\\_research/surveys\\_indices/cpi/2008/regional\\_highlights\\_factsheets](http://www.transparency.org/layout/set/print/policy_research/surveys_indices/cpi/2008/regional_highlights_factsheets). China and Mexico each had a score of 3.6; Thailand had a score of 3.5. Transparency Int’l, *Corruption Perceptions Index 2008*, [http://www.transparency.org/news\\_room/in\\_focus/2008/cpi2008/cpi\\_2008\\_table](http://www.transparency.org/news_room/in_focus/2008/cpi2008/cpi_2008_table). China and Mexico tied with several other countries for 72nd place on the 2008 Corruptions Perceptions Index; Thailand tied with several others for 80th. *Id.* The United States had a score of 7.7 and tied with the United Kingdom for a ranking of 16th. *Id.* Denmark, New Zealand, and Sweden topped the list as the countries with the lowest perceived levels of corruption, with scores of 9.3. *Id.*

country, this may be a relatively difficult task for foreign producers.<sup>152</sup> However, with respect to bribery and threats of violence, direct regulation leads to a counterintuitive result. The standard story is that a principal has more control over an employee than an independent contractor.<sup>153</sup> However, the social and political dynamics of extraterritorial regulation may severely limit the ability of an importing government to control bribery and threats of violence.

Consider the following. Unless a program of direct regulation is very small, it is unlikely to be able to rely solely on importing-country citizens as inspection staff. Importing-country citizens will almost certainly demand higher wages than citizens of many exporting countries, where prevailing wage rates are lower. Importing-country citizen wage demands are likely to be higher under many of the working conditions that would likely be included in a food inspection job located in a developing country. Many of these would be considered hardship locations, with significant health-related environmental problems, limited school facilities for children, and few employment opportunities for significant others. The basic job of inspection would almost certainly require travel in rural areas, where poor quality roads and different driving norms could lead to high accident rates that might justify hazard pay. The high wage rates likely demanded by importing-country citizen inspectors would combine with the inherent disadvantages that face any outsider taking on this type of role. Although some importing-country citizens would have, or be able to acquire, the relevant language skills, their ability to obtain relevant information would likely be less than that of native speakers familiar with local cultural norms.<sup>154</sup>

Accordingly, a program of direct regulation would likely involve the importing government supervising an inspection staff composed of citizens of the exporting country. These persons will be subject to similar social and cultural pressures as others operating in a high-corruption society. Unless an individual from a relatively low-corruption country is

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152. For example, foreign producers may be more limited in their ability to make campaign contributions than domestic producers or secure the appointment former employees as regulators in the importing country.

153. For example, this is part of the test the U.S. Internal Revenue Service uses in determining whether an individual is an employee or an independent contractor. *See generally* Rev. Rul. 87-41, 1987-1 C.B. 3121 (explaining that a high degree of control over an individual's behavior suggests that an individual is an employee rather than an independent contractor); I.R.S. Pub. 15-A, at 6-8 (Jan. 25, 2010), *available at* <http://www.irs.gov/pub/irs-pdf/p15a.pdf> (same).

154. This might be particularly true in rural areas, where most food production is likely to place.

sent to accompany the local inspectors on each field inspection, negating much of the cost advantage of local staff, direct employment of local inspectors by the importing government would not appear to address this information problem. In other words, the primary advantage of direct regulation—formal control of local inspectors—appears to be of relatively limited value in preventing bribery.

Moreover, a direct regulation program will likely be more limited in its ability to take action when it does discover a corruption problem. When an importing government is a direct employer of local inspectors, its personnel decisions can easily take on diplomatic ramifications. Although the decision to fire a single inspector may be unlikely to lead to an international crisis, experience with police departments suggests that corruption problems frequently become pervasive throughout an organization. It is not difficult to imagine that an importing government could feel constrained in its ability to fire a group of inspectors in, say, an economically depressed region of China.

Beyond firing, the importing government would also be limited in its ability to invoke criminal sanctions for bribery and threats. Extraterritorial criminal prosecutions of foreign nationals have historically carried significant political costs. Accordingly, an importing government may in practice be limited to turning its foreign employees over to local authorities for prosecution. Even this option has obvious problems. In particular, it would likely involve importing-country government employees testifying against their former coworkers in a criminal case in the exporting country—with the not-unlikely prospect of local courts concluding that the relevant allegation had not been proven. Of course, these prospects are not a bar to a direct regulation program, but they must be factored into a calculation of its total costs.

## *2. Other Problems*

In addition to principal-agent problems, a program of direct regulation carries other significant costs. First, a significant problem with direct regulation is the simple fact that on-the-ground regulators are employees of the importing government.<sup>155</sup> Their actions may be legally attributable to the importing government and will almost certainly be considered

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155. Similar problems would arise if they were direct contractors for the U.S. government, subject to detailed control by U.S. government employees.

attributable to the importing government by citizens of the exporting country. Accidents and abuses of authority are likely to take place in any regulatory program, and the direct involvement of the government may make them more difficult to resolve.

Second, funding is a substantial practical obstacle to a government-run program of foreign production process regulation. A program of direct extraterritorial regulation would have to be paid for either directly by the taxpayer in the importing country or through some system of overt user fees on the food import industry. Direct funding of a large-scale program appears to be a nonstarter in the current fiscal situation. However, user fees on the food import industry would likely fail under WTO rules unless similar fees were imposed on domestic producers.<sup>156</sup> This leaves a large outlay by the taxpayer in the importing country as the only way to fund a system of direct extraterritorial regulation.<sup>157</sup>

Moreover, to the extent that direct extraterritorial regulation is funded by the importing-country taxpayer—or in any manner that does not increase the price of imported products—it in effect provides an incentive for exporting countries to avoid developing their own domestic regulatory structures. In addition to reducing the price of imported food vis-à-vis domestically produced food, it would likely become a self-perpetuating policy. So long as the importing-country taxpayer is paying to make sure goods imported from China are safe, Chinese authorities have no incentive to spend their own tax dollars on making sure the foods it exports are safe. This gets the proper incentive structure backward. Given that exports are an engine for generating economic growth and hard currency reserves, countries rationally should be willing to provide some safety regulation for their export industry. Direct regulation of

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156. To the extent they were levied on food importers, they would likely be challenged by U.S. trading partners as nontariff barriers—or even explicit tariffs—violating WTO national treatment requirements. To the extent they were levied directly on foreign producers in particular countries, they would likely be challenged by U.S. trading partners as violating MFN status.

157. H.R. 2749 tries to sidestep this problem by imposing a \$500 fee on all food production facilities, whether domestic or foreign. However, this approach—imposing an equivalent fee on domestic and foreign facilities—still provides an incentive for foreign countries to avoid developing their own export safety programs. U.S. producers pay this fee on top of the portion of their taxes that already go to U.S. government food safety programs. Foreign producers pay this same fee whether or not their home country devotes significant tax resources to food export safety—Chinese producers pay the same \$500 fee that French producers do. Moreover, with respect to this specific bill, the Congressional Budget Office has estimated that this \$500 fee would fall \$2.2 billion short of the revenue needed to fund the inspection programs that H.R. 2749 requires. Jane Zhang, *House Passes Bill Giving FDA More Oversight of Food Safety*, WALL ST. J., July 31, 2009, at A3.

products produced in an underregulating country is likely to be a self-perpetuating policy with negative implications for both the economic growth rate and the trade balance in the importing country.

Third, direct regulation creates numerous logistical problems. Food production processes are widely dispersed. Food production typically begins with farming, ranching, or fishing operations. In developed countries, many of these operations are done on a large scale, with smaller scale operators moving increasingly toward higher-end products aimed at a particular market niche, such as high quality, environmental sustainability, or humane treatment of animals. In developing countries, however, many lower-end food products are produced by widely dispersed small-scale operators and later consolidated by a processor or packer. The sheer scope of these foreign food production processes suggests that there would be significant financial costs associated with any effort at direct extraterritorial regulation. Moreover, given that safety issues are different for each product category and subcategory,<sup>158</sup> there are reasons to doubt that managing such a program centrally would lead to economies of scale.

## *B. Delegation to Private Entity*

### *1. Generally*

A second direction for reform efforts is delegation to private entities. Delegation to a private entity introduces regulatory license problems not present in direct regulation. It also introduces an additional level of interest group capture risks because an interest group can capture either the supervisory agency in the importing government or the relevant private entity.<sup>159</sup> However, it should make it easier to deal with the principal-agent problem least effectively addressed by direct regulation: the problem of bribery and threats.

In some ways, delegated regulation can be thought of as a compromise approach. It both introduces an intermediary between the importing

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158. For example, green onion growing operations present different safety issues than wheat fields or oyster beds. Moreover, the set of risks applicable in Mexico or Canada may be different from those applicable in China.

159. This may make it easier to capture a subset of the regulatory program—such as the entity accrediting a particular industry or region—but more difficult to capture the full regulatory program for a particular country.

government and on-the-ground regulators and avoids a supervisory relationship between the importing government and a foreign government agency. These two features together reduce many of the diplomatic risks associated with either direct regulation or delegation to a foreign government agency. However, it also presents risks of private sector rent-seeking not present in the other approaches.

Delegation to a private entity also has several other features that may explain the recent interest it has generated. For example, it could permit an importing government to institute a program of foreign production process regulation without having to undertake day-to-day management of on-the-ground regulators. It would also permit *ex ante* regulation of production processes without direct employment of a large number of foreign staffers and the many complexities that could result.<sup>160</sup> A private entity could have significant freedom to fire corrupt or incompetent employees.<sup>161</sup> And delegation to a private entity may, though this is far from clear, make it possible to institute an industry-funded regulatory program in a manner that does not lead to trade disputes.<sup>162</sup>

## 2. *Adjusting Incentives*

Delegation to a private entity is also exciting as a regulatory proposal because it takes a top-down approach to creating private sector regulatory bodies that does not appear to have been tried previously on a large scale. Although private sector regulators play a substantial role in the United States,<sup>163</sup> most or all existing private sector regulators developed from the bottom up. Regulatory structures such as the securities industry self-regulatory organizations, the credit ratings companies, the higher education accreditation bodies, and organic-status certification providers existed before government regulation in these fields. When political or other reasons led the government to take on some regulatory role, it did so by giving official sanction to the decisions of these private sector organizations.

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160. For example: Are foreign employees agents of the U.S. government for purposes of tort liability? Does sovereign immunity apply to regulatory activities of the U.S. government abroad? Do their actions constitute state actions? Should they have U.S. government email addresses? Should they have any other access to, say, FDA computer systems?

161. Indeed, the very *absence* of U.S. control over the operations of the foreign entity would give it operational flexibility not possible with direct regulation.

162. See *infra* Part VI. The precise relationship between a delegated regulation regime and WTO rules is beyond the scope of this paper.

163. See *supra* Part II.A.4.

For those who believe there is a social benefit to relying on these private regulatory bodies rather than similar government structures, it is natural to ask whether effective private regulators can be developed through top-down government action. In other words, is it possible for a government to deliberately create a socially beneficial private regulation industry?

It is not surprising that interest in private regulators has been particularly strong when tied to conduct that occurs, at least in part, in a foreign country. In recent decades, several private organizations have developed thriving regulatory regimes that do not rely on a delegation of state authority. Instead, they rely on control of some type of claim in product labeling or advertising—often registered as a certification mark—to require parties to conform to specific behavioral requirements.<sup>164</sup>

Many questions remain about how effective these certification mark regimes are at enforcing their requirements. However, they have already generated a substantial academic literature and appear to have at least some influence on behavior in particular industries.

It is, of course, an empirical question whether the benefits associated with a government-created private regulatory structure would exceed the costs. Moreover, the absence of real-world examples suggests that empirical work on this issue is not yet possible. Accordingly, it may be premature to consider broad implementation of a delegated regulation regime. Instead, it may be more productive to focus on understanding the ways that the principal-agent problems associated with delegation to a private entity can be reduced. This might make it possible to avoid unnecessary mistakes in setting up a smaller scale pilot program.

#### *a. The Regulatory License Problem*

There are at least two possible ways to address the regulatory license problem. The first would be by delegating to a single private organization that would in effect have monopoly power; the second would be by creating a small group of competing organizations.

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164. See *supra* note 33. A significant third-party certification industry has developed in response to market pressures and legal risk associated with international business. See generally Blair et al., *supra* note 33, at 330–34. On the relationship between certification marks and the trademark registration system, see Manta, *supra* note 33, at 402–04.

The first approach, creating a private monopoly, appears to be the more promising option. The importing government could accredit only a single company to cover a single product category in a particular region. This accreditation could be for a limited duration,<sup>165</sup> renewable, and under some degree of regulatory supervision. The accredited company would have a monopoly on regulatory licenses and would be able to earn monopoly profits, perhaps with some upper limit set by regulation. Because the license would, in practice, be an entitlement to a future income stream, the company holding the entitlement would have a strong incentive to keep the importing government satisfied with its performance.

In this monopoly situation, there would be one key distinction from the regulatory license problem in the credit rating industry. In that industry, there have for long periods of time been only three Nationally Recognized Statistical Ratings Organizations (NRSROs), each of which has received a “no action” letter from the SEC through a somewhat opaque process.<sup>166</sup> Moreover, it does not appear that the SEC ever revoked one of these no action letters regarding NRSRO status.<sup>167</sup> Indeed, because the basis for this no action letter was that the particular credit rating agency was “nationally recognized,” it is not clear whether the SEC would have had statutory authority to revoke this designation absent some dramatic change in the credit rating agency’s reputation. Accordingly, a first problem with the NRSRO system was that there was

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165. This time period might be six months or one year at the beginning of such a program.

166. As of late 2002, a U.S. Senate committee found at least 8 federal statutes, 47 federal regulations, and 100 state laws and regulations that relied on NRSRO ratings. STAFF OF S. COMM. ON GOV’T AFFAIRS, 107TH CONG., FINANCIAL OVERSIGHT OF ENRON: THE SEC AND PRIVATE-SECTOR WATCHDOGS 102 (Comm. Print 2002). Credit ratings are also frequently used to trigger particular obligations in private contracts. *Id.* at 29. Despite its substantive importance, the SEC for three decades relied on the NRSRO concept without formally defining the term. Instead, agency staff developed an informal process by which it would issue “no action” letters to firms seeking to issue ratings that would satisfy regulatory NRSRO requirements. MICHAEL V. SEITZINGER ET AL., CONG. RESEARCH SERV., CREDIT RATING AGENCY REFORM ACT OF 2006, at 1–2 (2006); *see also* SEC. & EXCH. COMM’N, REPORT ON THE ROLE AND FUNCTION OF CREDIT RATING AGENCIES IN THE OPERATION OF THE SECURITIES MARKETS 9–10 (2003). After several unsuccessful reform efforts, both *credit-rating agency* and *NRSRO* were finally defined by statute in 2006. Credit Rating Agency Reform Act of 2006, Pub. L. No. 109-291, § 3(a), 120 Stat. 1327, 1328. Credit rating agencies wishing to be recognized as NRSROs were required to register with the SEC, and the agency was given general rulemaking authority to regulate NRSROs but not the methods by which they arrived at their ratings decisions. *Id.* § 4, 120 Stat. at 1329.

167. *Cf.* Lawrence J. White, *Good Intentions Gone Awry: A Policy Analysis of the SEC’s Regulation of the Bond Rating Industry* 6-7 (N.Y. Univ. Law & Econ. Working Papers, Paper No. 69), available at [http://lsr.nellco.org/nyu\\_lewp/69/](http://lsr.nellco.org/nyu_lewp/69/) (summarizing history of the SEC’s use of the NRSRO designation).



no credible threat that the three main NRSROs would lose their access to a valuable income stream.

A second problem with the NRSRO system was that the no action letter was an indefinite license—the SEC was not required to revisit its decision on any regular basis. On this analysis, a third potential problem with the NRSRO system was that the presence of some competition among rating companies actually reduced the quality of their ratings. Because NRSRO status did not guarantee monopoly profits, credit rating agencies had to compete with each other for a limited amount of ratings business.

Putting aside quality customer service, the two primary ways to compete in such a business would be to lower prices or lower rating standards. In a situation where you do not risk having your right to issue ratings revoked, lowering ratings standards is a more effective way to increase profits than lowering prices. There is at least some evidence to suggest that the NRSROs may have done this in connection with structured finance products.<sup>168</sup> However, in addition to the higher prices it would create, there is at least one significant problem with a monopoly approach: a threat to revoke a certification agency's accreditation might not be believable if there were no viable competitor to take its place.

Should the importing government choose the limited monopoly approach, its largest hurdle might be maintaining a credible threat to terminate an entity's rights under the program.<sup>169</sup> With no direct

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168. Cf. Sam Jones, *When Junk Was Gold—Part 2*, FIN. TIMES (London), Oct. 18, 2008, at 16 (reporting that a Moody's rating committee changed its methodology for rating "constant proportion debt obligation[s]" in early 2007 to preserve its "triple-A" status after discovering that correction of a coding error would otherwise have reduced the rating of that type of debt).

169. Problems with self-dealing by delegated regulation entities may be similar to the problems franchisors face in seeking to control franchisee behavior. In both situations, a principal seeks to control the behavior of an agent in ways that cannot be controlled through a contract, either because they cannot be precisely determined ex ante or because they cannot be cost effectively proven in court. Franchisors seek to get around the limits of incomplete contracts by structuring the relationship so that the franchisee has incentives to (1) maximize revenue to the franchisor; and (2) avoid diluting the value of the franchise brand. Francine Lafontaine & Emmanuel Raynaud, *Residual Claims and Self-Enforcement as Incentive Mechanisms in Franchise Contracts: Substitutes or Complements?*, in THE ECONOMICS OF CONTRACTS: THEORIES AND APPLICATIONS 315, 317–21 (Eric Brousseau & Jean-Michel Glachant eds., 2002). Franchisees are incentivized to maximize revenue through contracts that make them the residual claimant to current franchise revenues. *Id.* at 326–37. They are incentivized to avoid diluting the value of the franchise by self-enforcement mechanisms that (1) give them a reasonable expectation of access to a

competitors, who would step in to fill the terminated entity's regulatory role? The answer might be to accredit entities for a relatively narrow product category and to seek to ensure that there are competitors in related categories. If the importing government becomes dissatisfied with the entity accrediting shrimp aquaculture operations, the government can permit an entity accrediting aquaculture operations for another type of seafood to take its place.

An alternative approach to a government-sanctioned monopoly would be to set up a competition among accredited private entities. This would reduce the likelihood that the certification entities would be able to charge monopoly prices but would increase their incentives to increase profits by lowering their standards for certification. It would also create a situation in some ways uncomfortably similar to the competitive situation in the credit ratings industry before recent reforms.

With either a monopoly or a regulated-competition approach, the importing government would need to be careful to structure the initiative in a manner that avoids even the appearance that the exporting country was paying unreasonable fees. This might require some type of rate-setting process with participation by stakeholders in the exporting country, along with some avenue for those stakeholders to file complaints that would be taken into account in reaccreditation decisions.<sup>170</sup>

#### *b. Interest Group Capture*

In comparison to the regulatory license problem, adjusting incentives for interest group capture may be relatively easy in the context of delegation to a private entity. This is not to say that there are no risks of interest group capture—only that they do not appear to be increased substantially by the addition of a private sector entity.

To take pending U.S. legislation as an example, both the House and Senate bills contain detailed conflict of interest provisions.<sup>171</sup> Although minor loopholes may become apparent in actual practice, overall it appears that it will not be possible for anyone with a disclosed financial interest in the industry subject to certification to have any ownership

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future revenue stream; and (2) give the franchisor the right to terminate the relationship if the franchisee fails to comply with franchisor-specified behavior requirements. *Id.* at 329–30.

170. This would, of course, raise the administrative costs associated with delegation to a private entity.

171. H.R. 2749, 111th Cong. § 109 (2009); S. 510, 111th Cong. § 308 (2009). Both bills also require FDA to promulgate more detailed regulations on the subject. H.R. 2749 § 109; S. 510 § 308.

stake or operational role in the certification entity.<sup>172</sup> Although it is certainly possible—in the murky world of developing country corporate ownership structures—for someone with an undisclosed financial interest to become involved, this would appear to be a high-risk proposition. Accreditation would require the provision of substantial information to FDA.<sup>173</sup> False statements are likely to be criminally punishable under statutes prohibiting false statements to a federal official in an area of federal jurisdiction.

*c. Bribery and Corruption*

Bribery is one area in which it may be less necessary to adjust incentives in regulatory regime based on delegation to a private entity. It will be problematic under any of the three regulatory regimes, but delegation to a private entity can be structured to make this principal-agent problem easier to address than under the other two strategies.

The importing government would likely want to address bribery with two basic steps. First, it would need to design the process of accrediting and renewing the accreditation of private regulation entities to punish harshly any such entity whose employees are implicated in corrupt activities. Second, it would want to ensure that the importing government could not directly influence hiring and firing decisions by the private entity. This would permit the importing government to disclaim responsibility for individual termination decisions by private regulation entities.

*C. Delegation to a Foreign Government Agency*

A third direction for reform efforts is delegation to a foreign government agency. This exists in both traditional and modern forms. Its traditional form, which is less interesting for our purposes, is a simple determination that the exporting government's regulatory structures are equivalent to those of the importing country. This is typically used to permit the importing country to determine not to spend regulatory resources on an area that the exporting country regulates adequately.<sup>174</sup>

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172. H.R. 2749 § 109; S. 510 § 308.

173. H.R. 2749 § 109; S. 510 § 308.

174. *See supra* Part III.A.1 (discussing USDA determinations of equivalence).

The modern form looks to the foreign government agency not as an all-purpose regulator but as a substitute for a private certification entity. The primary example of this approach comes from the two bills currently pending before the U.S. Congress. Both the House and Senate bills permit the accreditation of foreign government agencies as third-party certifiers on terms roughly similar to those set out for private certification entities.<sup>175</sup> This appears to be an effort to keep foreign governments involved in regulating the safety of their exported food even when the country's regulatory structure cannot be found equivalent to that in the importing country.

This modern form of delegation to a foreign government agency raises concerns under each of the three key principal-agent problems.<sup>176</sup> This is in part because a foreign agency working on behalf of the importing government will almost certainly view the exporting government, rather than the importing government, as its primary "principal."

The severity of these problems will depend on whether the foreign government agency is permitted to charge a fee for its services. If it is not permitted to charge a fee and is instead funded by general tax revenues of the exporting country, it will respond primarily to incentive structures created by the way the foreign government manages the agency. Depending on the local political culture, these may include substantial problems relating to interest group capture, bribery, and threats.

However, if the foreign government agency is permitted to charge a fee for its services, delegation of regulatory authority to the foreign agency will create a regulatory license problem.<sup>177</sup> Because the foreign agency is not subject to the direction of politically responsible actors in the importing country, where the consumer-level effects of its decisions will be felt, it can be expected to respond to financial incentives much the same way that a private entity would. Like a private entity, a foreign agency authorized to collect a fee for certifying that a product complies with importing-country safety requirements will have an incentive to maximize its own revenue.

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175. See H.R. 2749 § 109; S. 510 § 308.

176. These problems may be specific to countries with underdeveloped regulatory regimes, where the importing country is seeking to incentivize those countries to apply a higher level of regulation than they apply to their domestic food supplies. In countries with developed regulatory regimes, it does not appear to create the same incentive problems to rely on the producing country to apply its standard food regulatory regime to products produced for export.

177. See *supra* Part IV.C.1.

This can be expected to result in the agency lowering its standards to the level that permits it to take in the maximum revenue without losing the right to sell its regulatory license. This will be most severe if the fees are used to fund the agency's own operations because the foreign agency's managers will then be able to internalize many of the benefits of additional revenue.<sup>178</sup> However, it should also exist to a lesser degree in situations in which the fees generated by the agency go to general revenues of the foreign government.

Industry capture risks will also be relatively severe with delegation to a foreign government agency. This is because reliance on a foreign government agency, rather than a private entity, introduces two—rather than one—new levels at which capture can take place.<sup>179</sup> Because any foreign government agency is likely to be subject to superior political authority,<sup>180</sup> would-be capturers could accomplish their goals either by capturing the foreign agency directly or by capturing its political masters in the foreign government.

For all self-dealing and capture problems, however, there is one fundamental difference between delegation to a private entity and delegation to a foreign government agency. The importing country will be able to exercise less control over the quality of certification decisions issued by a foreign government agency than it would over the certification decisions issued by a similar private entity. Whatever ability the importing country has to adjust the incentives that might affect a private entity, these will be less powerful with respect to an agency of a foreign government. There are at least two reasons for this.

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178. For example, the agency's managers could internalize the benefits in terms of salaries, perks, bureaucratic territory, or jobs for friends and relatives.

179. This distinguishes it from delegation to foreign private entity, which introduces only one new level where capture can take place.

180. This risk might be less severe if the relevant foreign government agencies had institutional guarantees of independence similar to those of statutorily independent agencies in the United States. *See generally* STEPHEN G. BREYER ET AL., ADMINISTRATIVE LAW AND REGULATORY POLICY: PROBLEMS, TEXT, AND CASES 100–02 (6th ed. 2006) (describing independent agencies). However, there does not appear to be any reason to believe that genuinely independent agencies are to be assigned safety responsibility for imported food in countries that are major sources of U.S. food imports. Indeed, in the United States, neither FDA nor USDA is a statutorily independent agency. *See* 21 U.S.C. § 393(d)(1) (appointment of Commissioner of Food and Drugs); 7 U.S.C. § 2202 (appointment of Secretary of Agriculture); *see also* PETER HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS (3d ed. 2007) (discussing President's ability to remove the Commissioner of Food and Drugs "for any or no reason").

First, the importing country will necessarily have less ability to sanction a foreign government agency than a similar private entity. To the extent that the importing country delegates regulatory authority to a private entity, it can effectively put that entity out of business by removing its right to grant a regulatory license. This is a simple, straightforward remedy to misbehavior by a private entity. Although there may be some limits on this authority<sup>181</sup>—not least because once an entity becomes part of the regulatory structure, it cannot easily be replaced until a substitute is available—the simple, on/off nature of this remedy is similar to a franchisor’s ability to terminate a franchise relationship.<sup>182</sup> Although the importing country could remove the authority of a foreign government agency to grant a regulatory license, this will not necessarily threaten either the existence of the agency itself or the jobs of its employees. They could all easily be reassigned by the foreign government to other work.

Second, any decision by the importing country to terminate a foreign agency’s right to grant a regulatory license could have diplomatic ramifications. Although this may not be particularly significant in terms of geopolitically and financially less influential countries, it could be quite significant with the importing country’s key trading partners.<sup>183</sup>

## VI. INTERNATIONAL TRADE

The post-WWII international trade system has opened numerous markets to foreign-produced goods and in turn helped to make a wide variety of imported products available to consumers in the developed world. However, its rules protecting market access have, perhaps necessarily, collateral consequences for safety regulation. Because discriminatory safety regulations are an effective means of favoring domestic products over imported products, a system protecting market access will likely impose some limitations on safety regulation. For the domestic policymaker, the challenge is to develop a regulatory scheme that increases product safety without leading to a WTO decision against

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181. Possibilities include limits on nonarbitrary termination that would likely be built into the program, similar to arrangements giving a franchisee a reasonable expectation of right to a future revenue stream during good behavior.

182. See Lafontaine & Raynaud, *supra* note 169, at 329–30.

183. For similar reasons, U.S. courts have traditionally applied the act of state doctrine to avoid passing on the validity of the actions of a foreign government taken on its own territory. See generally *Banco Nacional de Cuba v. Sabbatino*, 376 U.S. 398, 427–37 (1964).

the importing country.<sup>184</sup> Such a decision can have real consequences to the importing country because it authorizes the opposing party to impose retaliatory trade sanctions.

The core WTO treaty, the General Agreement on Tariffs and Trade of 1994 (GATT), contains two basic nondiscrimination requirements: (1) most favored nation (MFN) status;<sup>185</sup> and (2) national treatment provisions.<sup>186</sup> Broadly speaking, the first means that any requirement placed on products from one WTO member must apply equally to all WTO members.<sup>187</sup> The second means that any requirements placed on imported products must apply equally to domestically produced products.<sup>188</sup>

For food safety regulations, these general nondiscrimination requirements are supplemented by the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement provides generally that food safety measures must be necessary to protect human health,<sup>189</sup> based on scientific evidence<sup>190</sup> and appropriate risk assessment,<sup>191</sup> not arbitrarily discriminatory,<sup>192</sup> and no more restrictive than necessary.<sup>193</sup> Measures based on accepted international standards are presumed not to violate the SPS Agreement or the GATT.<sup>194</sup>

Delegated regulation must be implemented with care or it risks igniting a trade dispute. A delegated regulation regime that imposes requirements, such as third-party certification, on all foreign producers *and* all domestic

184. Although Congress has the power to violate U.S. WTO obligations under the last-in-time rule, these rules do appear to impose real constraints on the United States. In particular, the WTO dispute resolution system has made it more costly for the United States to ignore WTO obligations. See Rachel Brewster, *Rule-Based Dispute Resolution in International Trade Law*, 92 VA. L. REV. 251, 258–60, 266 (2006).

185. General Agreement on Tariffs and Trade art. I(1), Oct. 30, 1947, GATT 61 Stat. A-11, 55 U.N.T.S. 194 (1986).

186. *Id.* art. III(4).

187. Absent some exception to the MFN provisions, this means that any requirement applicable to milk products from China must also apply to milk products from France.

188. Absent some exception to the national treatment provisions, this means that any requirement applicable to foreign-produced green onions must also apply to domestically-produced green onions.

189. Agreement on the Application of Sanitary and Phytosanitary Measures art. 2(1), Apr. 15, 1994, WTO Agreement.

190. *Id.* art. 2(2).

191. *Id.* art. 5.

192. *Id.* art. 2(3).

193. *Id.* art. 2(2).

194. *Id.* art. 3(2).

producers for a particular product category would not violate MFN or national treatment requirements. However, once a state seeks to exempt domestic producers—perhaps because they are heavily regulated through domestic law—other states may object that this violates national treatment obligations.<sup>195</sup> Similarly, once a state attempts to exempt foreign producers in a particular set of countries, such as those with highly developed domestic regulatory systems, a nonexempt state may object that this violates MFN status.

However, the WTO regime does provide exceptions to national treatment and MFN requirements for health-related measures. GATT article XX(b) exempts measures “necessary to protect human, animal or plant life or health,” and appears to be an exception to both national treatment and MFN requirements.<sup>196</sup> This exception is subject to a broad requirement of legitimacy or good faith set out in the chapeau to GATT article XX. Measures restricting trade under articles XX(b) can be adopted only when they “are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail,” and “are not a disguised restriction on international trade.”<sup>197</sup>

Although it is impossible to predict how the WTO Appellate Body would react to a limited regime of delegated regulation, a few initial observations can be made. When interpreting the chapeau to article XX, the Appellate Body has been hostile to “rigid and unbending requirement[s]” imposed by a country that requires other WTO members to adopt exactly one particular regulatory approach.<sup>198</sup> However, the Appellate Body has been far more open to decisions by a country to limit market access to countries where there is a program “comparable in effectiveness” to that of the regulating country.<sup>199</sup> This suggests that a role for delegated regulation in an importing country’s regulatory scheme would not be categorically barred under WTO rules.

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195. A third-party certification requirement would be conceptualized as a potential nontariff barrier under international trade law.

196. General Agreement on Tariffs and Trade, *supra* note 185, art. XX(b).

197. *Id.* art. XX.

198. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products*, ¶ 177, WT/DS58/AB/R (Oct. 12, 1998).

199. Appellate Body Report, *United States—Import Prohibition of Certain Shrimp and Shrimp Products: Recourse to Article 21.5 of the DSU by Malaysia*, ¶ 144, WT/DS58/AB/RW (Oct. 22, 2001).



## VII. CONCLUSION

If there is one criticism that can be applied to almost all leading proposals for imported-food safety reform, it is that they try to do too much—and in the process risk doing too little. The current focus on “farm-to-fork” regulation risks spreading regulatory resources far too thin. It is not sufficient to declare that regulatory resources should be allocated using risk analysis techniques.<sup>200</sup> The global food supply is tremendously complicated, and levels of risks are heterogeneous across product categories, regions, and stages of production. Rather than seeking to improve safety across the entire food supply, it may be more effective to focus *ex ante* regulation efforts on discrete, identifiable risks.

Focusing on these principal-agent problems raises questions about any rush to implement a delegated regulation program on a large scale. Whether it is done through direct extraterritorial regulation or a delegated regulation alternative, inspection programs for foreign production face either high costs or self-dealing risks that may blunt the effectiveness of any large-scale regulatory program. However, this does not mean that it would be unproductive for FDA to move forward with a smaller scale program targeted toward high-risk product categories.

Should Congress pass a bill granting FDA authority to rely on delegated regulation, the agency could begin by licensing a small number of monopoly regulators in narrowly defined regions and product categories. Specific varieties of aquaculture seafood are possible candidates;<sup>201</sup> dairy products, particularly products involving powdered milk, may be

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200. See INTERAGENCY WORKING GROUP ON IMPORT SAFETY, ACTION PLAN FOR IMPORT SAFETY: A ROADMAP FOR CONTINUAL IMPROVEMENT (2007), available at <http://www.importsafety.gov/report/actionplan.pdf>; see also FOOD SAFETY WORKING GROUP, FOOD SAFETY WORKING GROUP: KEY FINDINGS, available at [http://www.foodsafetyworkinggroup.gov/FSWG\\_Key\\_Findings.pdf](http://www.foodsafetyworkinggroup.gov/FSWG_Key_Findings.pdf).

201. Currently, aquaculture products from numerous countries are subject to detention without physical examination at the U.S. border. See, e.g., U.S. Food & Drug Admin., Import Alert #16-131: Detention Without Physical Examination of Aquacultured Catfish, Basa, Shrimp, Dace, and Eel from China—Presence of New Animal Drugs and/or Unsafe Food Additives (Jan. 14, 2010), available at [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_33.html](http://www.accessdata.fda.gov/cms_ia/importalert_33.html); U.S. Food & Drug Admin., Import Alert #16-18: Detention Without Physical Examination of Shrimp (Apr. 8, 2010), available at [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_35.html](http://www.accessdata.fda.gov/cms_ia/importalert_35.html) (noting that fresh and frozen shrimp may be detained from Bangladesh, Hong Kong, India, Indonesia, Taiwan, and Thailand).

another.<sup>202</sup> FDA would then be faced with registering a manageable set of initial companies and would have the chance to develop sensible procedures and expertise before moving to a larger set of industries or regions. This would also incentivize producers in other industries to institute voluntary safety procedures that might prevent or slow an FDA decision to require delegated regulation in their industry.

Overall, the choice between these regulatory strategies implicates basic questions about the scope of government. Within an individual state, the choice between direct regulation and delegation to a private entity—between the size of the SEC and the size of its private sector counterpart, the Financial Institutions Regulatory Authority—is a question about the role of government and the value placed on competing power structures. In the multinational context, this choice expands to include the allocation of authority, and regulatory burden, between importing and exporting countries.

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202. Milk products from China are currently subject to detention without physical examination at the U.S. border. See U.S. Food & Drug Admin., Import Alert # 99-30: Detention Without Physical Examination of All Milk Products, Milk Derived Ingredients and Finished Food Products Containing Milk from China Due to the Presence of Melamine and/or Melamine Analogs (Oct. 2, 2009), *available at* [http://www.accessdata.fda.gov/cms\\_ia/importalert\\_401.html](http://www.accessdata.fda.gov/cms_ia/importalert_401.html).